付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	340		340		769		769	
with one or more adverse events	255	(75.0)	50	(14.7)	595	(77.4)	81	(10.5)
with no adverse events	85	(25.0)	290	(85.3)	174	(22.6)	688	(89.5)
Blood and lymphatic system disorders	**22**	**(6.5)**	**5**	**(1.5)**	**37**	**(4.8)**	**2**	**(0.3)**
Anaemia	14	(4.1)	4	(1.2)	19	(2.5)	0	(0.0)
Eosinophilia	2	(0.6)	0	(0.0)	6	(0.8)	0	(0.0)
Haemolytic anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Immune thrombocytopenic purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Iron deficiency anaemia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Leukocytosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Leukopenia	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)
Lymph node pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphadenitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphopenia	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)
Neutropenia	2	(0.6)	1	(0.3)	2	(0.3)	0	(0.0)
Pancytopenia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Thrombocytopenia	4	(1.2)	0	(0.0)	6	(0.8)	2	(0.3)
Cardiac disorders	**3**	**(0.9)**	**2**	**(0.6)**	**2**	**(0.3)**	**0**	**(0.0)**
Atrial fibrillation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Cyanosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Palpitations	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pericardial effusion	2	(0.6)	2	(0.6)	0	(0.0)	0	(0.0)
Pericarditis	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Tachycardia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Ear and labyrinth disorders	**3**	**(0.9)**	**0**	**(0.0)**	**8**	**(1.0)**	**0**	**(0.0)**
External ear pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hearing impaired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vertigo	2	(0.6)	0	(0.0)	8	(1.0)	0	(0.0)
Vertigo positional	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Endocrine disorders	**34**	**(10.0)**	**2**	**(0.6)**	**69**	**(9.0)**	**6**	**(0.8)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	4	(0.5)	2	(0.3)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)
Endocrine disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Hyperparathyroidism	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperthyroidism	9	(2.6)	0	(0.0)	15	(2.0)	1	(0.1)
Hypophysitis	3	(0.9)	2	(0.6)	2	(0.3)	1	(0.1)
Hypopituitarism	1	(0.3)	0	(0.0)	2	(0.3)	2	(0.3)
Hypothyroidism	23	(6.8)	0	(0.0)	49	(6.4)	0	(0.0)
Primary hypothyroidism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroiditis	3	(0.9)	0	(0.0)	3	(0.4)	0	(0.0)
Eye disorders	**20**	**(5.9)**	**0**	**(0.0)**	**39**	**(5.1)**	**2**	**(0.3)**
Abnormal sensation in eye	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Asthenopia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Conjunctival hyperaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diplopia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dry eye	4	(1.2)	0	(0.0)	6	(0.8)	0	(0.0)
Eczema eyelids	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Eye disorder	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Eye pain	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Eye pruritus	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Eye swelling	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Eyelash discolouration	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)
Eyelid disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelid exfoliation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Eyelid oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Foreign body sensation in eyes	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Growth of eyelashes	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypopigmentation of eyelid	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Iridocyclitis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Iritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Lacrimation increased	3	(0.9)	0	(0.0)	2	(0.3)	0	(0.0)
Macular degeneration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Ocular discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ocular hyperaemia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Papilloedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Periorbital oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Photophobia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Photopsia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Scleritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Uveitis	1	(0.3)	0	(0.0)	6	(0.8)	0	(0.0)
Vision blurred	3	(0.9)	0	(0.0)	6	(0.8)	0	(0.0)
Visual impairment	5	(1.5)	0	(0.0)	3	(0.4)	0	(0.0)
Vitreous floaters	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal disorders	**88**	**(25.9)**	**10**	**(2.9)**	**232**	**(30.2)**	**22**	**(2.9)**
Abdominal discomfort	2	(0.6)	0	(0.0)	6	(0.8)	0	(0.0)
Abdominal distension	2	(0.6)	0	(0.0)	6	(0.8)	0	(0.0)
Abdominal pain	12	(3.5)	0	(0.0)	16	(2.1)	1	(0.1)
Abdominal pain lower	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Abdominal pain upper	2	(0.6)	0	(0.0)	13	(1.7)	0	(0.0)
Aerophagia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aphthous stomatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aptyalism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ascites	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Autoimmune pancreatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Chapped lips	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cheilitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Colitis	3	(0.9)	2	(0.6)	14	(1.8)	9	(1.2)
Colitis microscopic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	13	(3.8)	0	(0.0)	23	(3.0)	0	(0.0)
Defaecation urgency	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Diarrhoea	40	(11.8)	1	(0.3)	107	(13.9)	7	(0.9)
Dry mouth	5	(1.5)	0	(0.0)	19	(2.5)	0	(0.0)
Duodenitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Dyspepsia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Dysphagia	3	(0.9)	1	(0.3)	2	(0.3)	0	(0.0)
Enteritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Enterocolitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Epigastric discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Faeces hard	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Faeces soft	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Flatulence	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)
Food poisoning	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Frequent bowel movements	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)
Gastritis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrointestinal sounds abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrooesophageal reflux disease	3	(0.9)	0	(0.0)	2	(0.3)	0	(0.0)
Gingival bleeding	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gingival pain	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haemorrhoids	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Ileus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Intestinal obstruction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Intussusception	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Irritable bowel syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lip oedema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Mouth ulceration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Mucous stools	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	26	(7.6)	1	(0.3)	94	(12.2)	2	(0.3)
Odynophagia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oesophagitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Oral mucosal blistering	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral pain	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Pancreatitis	1	(0.3)	0	(0.0)	2	(0.3)	1	(0.1)
Periodontal disease	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Rectal haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Regurgitation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Retching	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Salivary gland disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sensitivity of teeth	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Small intestinal perforation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Stomatitis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Tongue discolouration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tooth demineralisation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Tooth disorder	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Upper gastrointestinal haemorrhage	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Vomiting	11	(3.2)	3	(0.9)	29	(3.8)	1	(0.1)
General disorders and administration site conditions	**135**	**(39.7)**	**14**	**(4.1)**	**322**	**(41.9)**	**9**	**(1.2)**
Adverse drug reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Asthenia	17	(5.0)	3	(0.9)	69	(9.0)	2	(0.3)
Axillary pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Chest discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Chest pain	2	(0.6)	1	(0.3)	5	(0.7)	0	(0.0)
Chills	16	(4.7)	0	(0.0)	24	(3.1)	0	(0.0)
Death	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Face oedema	3	(0.9)	0	(0.0)	1	(0.1)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Fatigue	90	(26.5)	8	(2.4)	215	(28.0)	4	(0.5)
Feeling cold	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Gait disturbance	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
General physical health deterioration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Generalised oedema	2	(0.6)	2	(0.6)	2	(0.3)	0	(0.0)
Hyperthermia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Hypothermia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Inflammation	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)
Inflammatory pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Influenza like illness	4	(1.2)	0	(0.0)	19	(2.5)	0	(0.0)
Injection site extravasation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Injection site reaction	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Local swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Localised oedema	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Malaise	4	(1.2)	0	(0.0)	3	(0.4)	0	(0.0)
Mucosal discolouration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Mucosal inflammation	4	(1.2)	0	(0.0)	7	(0.9)	1	(0.1)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oedema	2	(0.6)	0	(0.0)	5	(0.7)	0	(0.0)
Oedema peripheral	10	(2.9)	0	(0.0)	11	(1.4)	0	(0.0)

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	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Pain	4	(1.2)	0	(0.0)	4	(0.5)	0	(0.0)
Performance status decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pyrexia	10	(2.9)	0	(0.0)	36	(4.7)	1	(0.1)
Swelling	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Systemic inflammatory response syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Temperature intolerance	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Thirst	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Xerosis	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)
Hepatobiliary disorders	**6**	**(1.8)**	**3**	**(0.9)**	**9**	**(1.2)**	**6**	**(0.8)**
Autoimmune hepatitis	4	(1.2)	3	(0.9)	3	(0.4)	2	(0.3)
Cholestasis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Drug-induced liver injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Hepatitis	1	(0.3)	0	(0.0)	3	(0.4)	3	(0.4)
Hyperbilirubinaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Immune system disorders	**3**	**(0.9)**	**0**	**(0.0)**	**10**	**(1.3)**	**2**	**(0.3)**
Allergy to animal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Atopy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Autoimmune disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cytokine release syndrome	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Drug hypersensitivity	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Hypersensitivity	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)
Sarcoidosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Seasonal allergy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Infections and infestations	**10**	**(2.9)**	**0**	**(0.0)**	**28**	**(3.6)**	**4**	**(0.5)**
Bacterial sepsis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Candida infection	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Clostridium difficile infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Conjunctivitis	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)
Diverticulitis	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Encephalitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Erysipelas	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Folliculitis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Fungal skin infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastroenteritis viral	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Herpes zoster	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hordeolum	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Influenza	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Lung infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymph gland infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nasopharyngitis	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Oral candidiasis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Oral fungal infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oral herpes	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Otitis media	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pharyngitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Respiratory tract infection	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Rhinitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sinusitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Skin infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Staphylococcal infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tinea versicolour	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tooth abscess	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tuberculosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Upper respiratory tract infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urinary tract infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Injury, poisoning and procedural complications	**1**	**(0.3)**	**0**	**(0.0)**	**15**	**(2.0)**	**0**	**(0.0)**
Chillblains	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Contusion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Excoriation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Incision site complication	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Infusion related reaction	0	(0.0)	0	(0.0)	9	(1.2)	0	(0.0)
Procedural pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Radiation skin injury	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sunburn	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Tooth fracture	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Investigations	**43**	**(12.6)**	**5**	**(1.5)**	**91**	**(11.8)**	**8**	**(1.0)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Alanine aminotransferase	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Alanine aminotransferase increased	11	(3.2)	0	(0.0)	21	(2.7)	3	(0.4)
Amylase increased	3	(0.9)	1	(0.3)	0	(0.0)	0	(0.0)
Aortic bruit	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aspartate aminotransferase increased	11	(3.2)	1	(0.3)	19	(2.5)	4	(0.5)
Autoantibody positive	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bilirubin conjugated increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood alkaline phosphatase decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood alkaline phosphatase increased	2	(0.6)	0	(0.0)	7	(0.9)	0	(0.0)
Blood bicarbonate decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood bilirubin increased	3	(0.9)	0	(0.0)	3	(0.4)	0	(0.0)
Blood calcium increased	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Blood cholesterol increased	2	(0.6)	0	(0.0)	2	(0.3)	0	(0.0)
Blood corticotrophin decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood corticotrophin increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood cortisol decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood creatine phosphokinase increased	2	(0.6)	1	(0.3)	1	(0.1)	1	(0.1)
Blood creatinine increased	1	(0.3)	0	(0.0)	7	(0.9)	0	(0.0)
Blood glucose abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood glucose increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Blood lactate dehydrogenase increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood luteinising hormone decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Blood parathyroid hormone increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood phosphorus decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood testosterone decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Blood thyroid stimulating hormone decreased	2	(0.6)	0	(0.0)	8	(1.0)	0	(0.0)
Blood thyroid stimulating hormone increased	2	(0.6)	0	(0.0)	7	(0.9)	0	(0.0)
Blood triglycerides increased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Blood urea increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Body temperature increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
C-reactive protein increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Electrocardiogram QT prolonged	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Electrocardiogram repolarisation abnormality	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eosinophil count increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gamma-glutamyltransferase increased	3	(0.9)	2	(0.6)	2	(0.3)	1	(0.1)
Haemoglobin decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hepatic enzyme increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lipase	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lipase increased	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Liver function test abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphocyte count decreased	3	(0.9)	1	(0.3)	5	(0.7)	1	(0.1)
Neutrophil count decreased	2	(0.6)	0	(0.0)	4	(0.5)	0	(0.0)
Neutrophil count increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Platelet count decreased	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)
Thyroglobulin increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroxine decreased	1	(0.3)	0	(0.0)	6	(0.8)	0	(0.0)
Thyroxine free increased	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Thyroxine increased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Transaminases increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tri-iodothyronine decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tri-iodothyronine increased	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Weight decreased	4	(1.2)	0	(0.0)	15	(2.0)	0	(0.0)
Weight increased	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
White blood cell count decreased	2	(0.6)	0	(0.0)	3	(0.4)	0	(0.0)
White blood cell count increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders	**37**	**(10.9)**	**3**	**(0.9)**	**85**	**(11.1)**	**11**	**(1.4)**
Cell death	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Decreased appetite	23	(6.8)	0	(0.0)	54	(7.0)	2	(0.3)
Dehydration	3	(0.9)	1	(0.3)	5	(0.7)	0	(0.0)
Diabetes mellitus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Electrolyte imbalance	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Failure to thrive	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fluid overload	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Fluid retention	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Gout	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypercalcaemia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Hypercholesterolaemia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperglycaemia	2	(0.6)	0	(0.0)	4	(0.5)	1	(0.1)
Hyperkalaemia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperlipidaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypertriglyceridaemia	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)
Hyperuricaemia	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)
Hypoalbuminaemia	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)
Hypocalcaemia	1	(0.3)	0	(0.0)	7	(0.9)	0	(0.0)
Hypokalaemia	0	(0.0)	0	(0.0)	8	(1.0)	2	(0.3)
Hypomagnesaemia	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)
Hyponatraemia	2	(0.6)	0	(0.0)	5	(0.7)	5	(0.7)
Hypophosphataemia	3	(0.9)	0	(0.0)	4	(0.5)	0	(0.0)
Increased appetite	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Insulin resistant diabetes	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Iron deficiency	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Vitamin B12 deficiency	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal and connective tissue disorders	**71**	**(20.9)**	**4**	**(1.2)**	**159**	**(20.7)**	**5**	**(0.7)**
Ankylosing spondylitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Arthralgia	41	(12.1)	1	(0.3)	93	(12.1)	2	(0.3)
Arthritis	2	(0.6)	0	(0.0)	4	(0.5)	0	(0.0)
Arthropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Back pain	7	(2.1)	0	(0.0)	12	(1.6)	0	(0.0)
Bone pain	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Chondrocalcinosis pyrophosphate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fibromyalgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Flank pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Groin pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Growing pains	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Joint effusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Joint range of motion decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Joint stiffness	3	(0.9)	0	(0.0)	4	(0.5)	0	(0.0)
Joint swelling	2	(0.6)	0	(0.0)	5	(0.7)	0	(0.0)
Limb discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle atrophy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle spasms	6	(1.8)	0	(0.0)	9	(1.2)	0	(0.0)
Muscle tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscle twitching	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Muscular weakness	7	(2.1)	2	(0.6)	10	(1.3)	0	(0.0)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Musculoskeletal discomfort	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Musculoskeletal pain	2	(0.6)	0	(0.0)	8	(1.0)	1	(0.1)
Musculoskeletal stiffness	3	(0.9)	0	(0.0)	10	(1.3)	0	(0.0)
Myalgia	19	(5.6)	2	(0.6)	39	(5.1)	0	(0.0)
Myopathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Myositis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Neck pain	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)
Nodal osteoarthritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Osteoarthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pain in extremity	4	(1.2)	0	(0.0)	11	(1.4)	1	(0.1)
Pain in jaw	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)
Plantar fasciitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Polyarthritis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Polymyalgia rheumatica	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sjogren's syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Synovitis	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Tendon pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tendonitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tenosynovitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Torticollis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**3**	**(0.9)**	**0**	**(0.0)**	**9**	**(1.2)**	**0**	**(0.0)**
Acrochordon	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Infected neoplasm	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Keratoacanthoma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Malignant melanoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Melanocytic naevus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Metastatic pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neoplasm swelling	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oncologic complication	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Seborrhoeic keratosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin papilloma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tumour pain	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)
Nervous system disorders	**48**	**(14.1)**	**2**	**(0.6)**	**85**	**(11.1)**	**5**	**(0.7)**
Ageusia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Amnesia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Amnestic disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Balance disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Brain oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Carpal tunnel syndrome	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cognitive disorder	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)
Convulsion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Depressed level of consciousness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Disturbance in attention	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Dizziness	4	(1.2)	0	(0.0)	5	(0.7)	0	(0.0)
Dysaesthesia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Dysarthria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dysgeusia	6	(1.8)	0	(0.0)	14	(1.8)	0	(0.0)
Encephalopathy	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Epilepsy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Guillain-Barre syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Haemorrhagic stroke	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Headache	16	(4.7)	1	(0.3)	35	(4.6)	1	(0.1)
Hyperaesthesia	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Hypersomnia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Hypoaesthesia	4	(1.2)	0	(0.0)	2	(0.3)	0	(0.0)
Hypogeusia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Hypotonia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Judgement impaired	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lethargy	5	(1.5)	0	(0.0)	3	(0.4)	0	(0.0)
Loss of consciousness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Memory impairment	3	(0.9)	0	(0.0)	3	(0.4)	0	(0.0)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Neuralgia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Neuropathy peripheral	3	(0.9)	0	(0.0)	6	(0.8)	0	(0.0)
Optic neuritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Paraesthesia	2	(0.6)	0	(0.0)	9	(1.2)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Partial seizures	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral sensory neuropathy	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Polyneuropathy	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Poor quality sleep	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Presyncope	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Restless legs syndrome	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sciatica	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sensory disturbance	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Syncope	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tremor	4	(1.2)	0	(0.0)	0	(0.0)	0	(0.0)
Psychiatric disorders	**6**	**(1.8)**	**1**	**(0.3)**	**20**	**(2.6)**	**0**	**(0.0)**
Affective disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Agitation	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Anxiety	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Confusional state	1	(0.3)	1	(0.3)	3	(0.4)	0	(0.0)
Depression	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Disorientation	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Dysphoria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hallucination	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Insomnia	2	(0.6)	0	(0.0)	6	(0.8)	0	(0.0)
Irritability	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Libido decreased	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Middle insomnia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Phobia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sleep disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Trance	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Renal and urinary disorders	**3**	**(0.9)**	**0**	**(0.0)**	**9**	**(1.2)**	**1**	**(0.1)**
Chromaturia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Dysuria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haematuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pollakiuria	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Proteinuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	3	(0.4)	1	(0.1)
Renal failure acute	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Renal failure chronic	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Renal impairment	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tubulointerstitial nephritis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Urine odour abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders	**5**	**(1.5)**	**1**	**(0.3)**	**9**	**(1.2)**	**0**	**(0.0)**
Amenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Breast pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Breast tenderness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dysmenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erectile dysfunction	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)
Genital rash	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haematospermia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Menorrhagia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nipple pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nipple swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pelvic pain	2	(0.6)	1	(0.3)	2	(0.3)	0	(0.0)
Pruritus genital	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Scrotal erythema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vulvovaginal pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**49**	**(14.4)**	**5**	**(1.5)**	**90**	**(11.7)**	**7**	**(0.9)**
Asthma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Bronchial hyperreactivity	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cough	22	(6.5)	0	(0.0)	39	(5.1)	0	(0.0)
Dysphonia	2	(0.6)	1	(0.3)	0	(0.0)	0	(0.0)
Dyspnoea	17	(5.0)	3	(0.9)	32	(4.2)	3	(0.4)
Dyspnoea exertional	4	(1.2)	0	(0.0)	4	(0.5)	0	(0.0)
Epistaxis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Haemoptysis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Hiccups	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Interstitial lung disease	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)
Laryngeal discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Laryngeal inflammation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Nasal congestion	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)
Nasal dryness	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nasal mucosal disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Oropharyngeal pain	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)
Painful respiration	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Pleural effusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pleuritic pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pneumonitis	3	(0.9)	1	(0.3)	15	(2.0)	3	(0.4)
Productive cough	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Pulmonary congestion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pulmonary oedema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Respiratory failure	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rhinitis allergic	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rhinorrhoea	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Sinus congestion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sneezing	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Throat irritation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Wheezing	2	(0.6)	0	(0.0)	4	(0.5)	0	(0.0)
Skin and subcutaneous tissue disorders	**147**	**(43.2)**	**2**	**(0.6)**	**347**	**(45.1)**	7	**(0.9)**
Acne	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Actinic keratosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Alopecia	6	(1.8)	0	(0.0)	6	(0.8)	0	(0.0)
Blister	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)
Dermatitis acneiform	4	(1.2)	0	(0.0)	5	(0.7)	0	(0.0)
Dermatitis allergic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis exfoliative	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dermatitis psoriasiform	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Drug eruption	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dry skin	12	(3.5)	0	(0.0)	25	(3.3)	0	(0.0)
Eczema	3	(0.9)	0	(0.0)	12	(1.6)	0	(0.0)
Eczema asteatotic	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erythema	11	(3.2)	0	(0.0)	14	(1.8)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Erythema nodosum	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Exfoliative rash	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Granuloma skin	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hair colour changes	4	(1.2)	0	(0.0)	3	(0.4)	0	(0.0)
Hair growth abnormal	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)
Hair texture abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperhidrosis	3	(0.9)	0	(0.0)	5	(0.7)	0	(0.0)
Hyperkeratosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypertrichosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Ichthyosis acquired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Keratosis pilaris	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lichen sclerosus	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lichenoid keratosis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Linear IgA disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Macule	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Madarosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nail discolouration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Nail disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nail growth abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Neutrophilic dermatosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Night sweats	7	(2.1)	0	(0.0)	11	(1.4)	0	(0.0)
Onychoclasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Pain of skin	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	2	(0.6)	0	(0.0)	1	(0.1)	0	(0.0)
Panniculitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Papule	2	(0.6)	0	(0.0)	4	(0.5)	0	(0.0)
Parapsoriasis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Photosensitivity reaction	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)
Pigmentation disorder	2	(0.6)	0	(0.0)	0	(0.0)	0	(0.0)
Prurigo	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Pruritus	76	(22.4)	0	(0.0)	160	(20.8)	1	(0.1)
Pruritus generalised	2	(0.6)	0	(0.0)	9	(1.2)	0	(0.0)
Psoriasis	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)
Purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pustular psoriasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Rash	58	(17.1)	0	(0.0)	117	(15.2)	1	(0.1)
Rash erythematous	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)
Rash follicular	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Rash generalised	3	(0.9)	0	(0.0)	6	(0.8)	1	(0.1)
Rash macular	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)
Rash maculo-papular	9	(2.6)	1	(0.3)	28	(3.6)	3	(0.4)
Rash papular	2	(0.6)	0	(0.0)	5	(0.7)	0	(0.0)
Rash pruritic	2	(0.6)	0	(0.0)	7	(0.9)	0	(0.0)
Rash vesicular	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Rosacea	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Scab	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Sebaceous gland disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Seborrhoeic dermatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin burning sensation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin depigmentation	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Skin discolouration	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Skin disorder	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin exfoliation	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Skin haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Skin hyperpigmentation	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)
Skin hypopigmentation	3	(0.9)	0	(0.0)	15	(2.0)	0	(0.0)
Skin irritation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin lesion	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)
Skin mass	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)
Skin ulcer	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)
Solar dermatitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Stevens-Johnson syndrome	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Transient acantholytic dermatosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Urticaria	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)
Urticaria papular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vitiligo	25	(7.4)	0	(0.0)	70	(9.1)	0	(0.0)
Xanthelasma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Xeroderma	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Vascular disorders	**6**	**(1.8)**	**1**	**(0.3)**	**21**	**(2.7)**	**1**	**(0.1)**
Flushing	0	(0.0)	0	(0.0)	6	(0.8)	0	(0.0)
Haematoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hot flush	3	(0.9)	0	(0.0)	6	(0.8)	0	(0.0)
Hypertension	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)
Hypotension	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)
Intermittent claudication	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Jugular vein thrombosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)
Lymphoedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pallor	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral coldness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Peripheral ischaemia	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)
Raynaud's phenomenon	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)
Varicophlebitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vasculitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Venous thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	458		458		1567		1567	
with one or more adverse events	371	(81.0)	71	(15.5)	1221	(77.9)	202	(12.9)
with no adverse events	87	(19.0)	387	(84.5)	346	(22.1)	1365	(87.1)
Blood and lymphatic system disorders	**23**	**(5.0)**	7	**(1.5)**	**82**	**(5.2)**	**14**	**(0.9)**
Anaemia	12	(2.6)	3	(0.7)	45	(2.9)	7	(0.4)
Eosinophilia	2	(0.4)	0	(0.0)	10	(0.6)	0	(0.0)
Haemolytic anaemia	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Immune thrombocytopenic purpura	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Iron deficiency anaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Leukocytosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Leukopenia	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Lymph node pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphadenitis	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Lymphopenia	2	(0.4)	1	(0.2)	7	(0.4)	1	(0.1)
Neutropenia	0	(0.0)	0	(0.0)	4	(0.3)	1	(0.1)
Pancytopenia	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Thrombocytopenia	4	(0.9)	0	(0.0)	14	(0.9)	2	(0.1)
Cardiac disorders	**5**	**(1.1)**	**1**	**(0.2)**	**10**	**(0.6)**	**3**	**(0.2)**
Atrial fibrillation	1	(0.2)	1	(0.2)	2	(0.1)	1	(0.1)
Cyanosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Palpitations	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Pericardial effusion	1	(0.2)	0	(0.0)	3	(0.2)	2	(0.1)
Pericarditis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Tachycardia	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Ear and labyrinth disorders	**2**	**(0.4)**	**0**	**(0.0)**	**13**	**(0.8)**	**0**	**(0.0)**
External ear pain	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Hearing impaired	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Vertigo	0	(0.0)	0	(0.0)	10	(0.6)	0	(0.0)
Vertigo positional	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Endocrine disorders	**55**	**(12.0)**	**6**	**(1.3)**	**158**	**(10.1)**	**14**	**(0.9)**
Adrenal insufficiency	3	(0.7)	2	(0.4)	7	(0.4)	4	(0.3)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	4	(0.3)	0	(0.0)
Endocrine disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Hyperparathyroidism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperthyroidism	21	(4.6)	1	(0.2)	45	(2.9)	2	(0.1)
Hypophysitis	0	(0.0)	0	(0.0)	5	(0.3)	3	(0.2)
Hypopituitarism	2	(0.4)	1	(0.2)	5	(0.3)	3	(0.2)
Hypothyroidism	42	(9.2)	2	(0.4)	114	(7.3)	2	(0.1)
Primary hypothyroidism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroiditis	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Eye disorders	**27**	**(5.9)**	**0**	**(0.0)**	**86**	**(5.5)**	**2**	**(0.1)**
Abnormal sensation in eye	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Asthenopia	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Conjunctival hyperaemia	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Diplopia	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Dry eye	7	(1.5)	0	(0.0)	17	(1.1)	0	(0.0)
Eczema eyelids	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eye disorder	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Eye pain	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Eye pruritus	2	(0.4)	0	(0.0)	4	(0.3)	0	(0.0)
Eye swelling	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Eyelash discolouration	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Eyelid disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelid exfoliation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelid oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Foreign body sensation in eyes	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Growth of eyelashes	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypopigmentation of eyelid	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Iridocyclitis	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Iritis	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)
Lacrimation increased	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Macular degeneration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ocular discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ocular hyperaemia	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Papilloedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Periorbital oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Photophobia	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Photopsia	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Scleritis	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Uveitis	1	(0.2)	0	(0.0)	8	(0.5)	0	(0.0)
Vision blurred	2	(0.4)	0	(0.0)	11	(0.7)	0	(0.0)
Visual impairment	3	(0.7)	0	(0.0)	11	(0.7)	0	(0.0)
Vitreous floaters	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Gastrointestinal disorders	**165**	**(36.0)**	**19**	**(4.1)**	**485**	**(31.0)**	**51**	**(3.3)**
Abdominal discomfort	3	(0.7)	0	(0.0)	11	(0.7)	0	(0.0)
Abdominal distension	5	(1.1)	0	(0.0)	13	(0.8)	0	(0.0)
Abdominal pain	21	(4.6)	0	(0.0)	49	(3.1)	1	(0.1)
Abdominal pain lower	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Abdominal pain upper	7	(1.5)	0	(0.0)	22	(1.4)	0	(0.0)
Aerophagia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aphthous stomatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aptyalism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ascites	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Autoimmune pancreatitis	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Chapped lips	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cheilitis	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Colitis	6	(1.3)	5	(1.1)	23	(1.5)	16	(1.0)
Colitis microscopic	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Constipation	16	(3.5)	0	(0.0)	52	(3.3)	0	(0.0)
Defaecation urgency	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Diarrhoea	89	(19.4)	10	(2.2)	236	(15.1)	18	(1.1)
Dry mouth	29	(6.3)	0	(0.0)	53	(3.4)	0	(0.0)
Duodenitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dyspepsia	5	(1.1)	0	(0.0)	7	(0.4)	0	(0.0)
Dysphagia	1	(0.2)	0	(0.0)	6	(0.4)	1	(0.1)
Enteritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Enterocolitis	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Epigastric discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Faeces hard	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Faeces soft	1	(0.2)	0	(0.0)	4	(0.3)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Flatulence	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Food poisoning	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Frequent bowel movements	0	(0.0)	0	(0.0)	4	(0.3)	0	(0.0)
Gastritis	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Gastrointestinal disorder	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Gastrointestinal sounds abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrooesophageal reflux disease	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Gingival bleeding	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gingival pain	1	(0.2)	0	(0.0)	4	(0.3)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haemorrhoids	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Ileus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Intestinal obstruction	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Intussusception	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Irritable bowel syndrome	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Lip oedema	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Mouth ulceration	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Mucous stools	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nausea	60	(13.1)	1	(0.2)	180	(11.5)	4	(0.3)
Odynophagia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oesophagitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Oral mucosal blistering	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oral pain	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Pancreatitis	0	(0.0)	0	(0.0)	3	(0.2)	1	(0.1)
Periodontal disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rectal haemorrhage	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Regurgitation	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Retching	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Salivary gland disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sensitivity of teeth	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Small intestinal perforation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Stomatitis	2	(0.4)	0	(0.0)	4	(0.3)	0	(0.0)
Tongue discolouration	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tooth demineralisation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Tooth disorder	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Upper gastrointestinal haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Vomiting	20	(4.4)	2	(0.4)	60	(3.8)	6	(0.4)
General disorders and administration site conditions	**222**	**(48.5)**	**7**	**(1.5)**	**679**	**(43.3)**	**30**	**(1.9)**
Adverse drug reaction	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Asthenia	54	(11.8)	2	(0.4)	140	(8.9)	7	(0.4)
Axillary pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Chest discomfort	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Chest pain	3	(0.7)	0	(0.0)	10	(0.6)	1	(0.1)
Chills	15	(3.3)	0	(0.0)	55	(3.5)	0	(0.0)
Death	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Face oedema	0	(0.0)	0	(0.0)	4	(0.3)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Fatigue	143	(31.2)	4	(0.9)	448	(28.6)	16	(1.0)
Feeling cold	2	(0.4)	0	(0.0)	4	(0.3)	0	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Gait disturbance	1	(0.2)	0	(0.0)	4	(0.3)	0	(0.0)
General physical health deterioration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Generalised oedema	1	(0.2)	0	(0.0)	5	(0.3)	2	(0.1)
Hyperthermia	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Hypothermia	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Inflammation	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Inflammatory pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Influenza like illness	7	(1.5)	0	(0.0)	30	(1.9)	0	(0.0)
Injection site extravasation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Injection site reaction	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Local swelling	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Localised oedema	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Malaise	1	(0.2)	0	(0.0)	8	(0.5)	0	(0.0)
Mucosal discolouration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Mucosal inflammation	3	(0.7)	0	(0.0)	14	(0.9)	1	(0.1)
Non-cardiac chest pain	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oedema	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Oedema peripheral	12	(2.6)	0	(0.0)	33	(2.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Pain	1	(0.2)	1	(0.2)	9	(0.6)	1	(0.1)
Performance status decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral swelling	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pyrexia	27	(5.9)	0	(0.0)	73	(4.7)	1	(0.1)
Swelling	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Systemic inflammatory response syndrome	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Temperature intolerance	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Thirst	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Xerosis	0	(0.0)	0	(0.0)	4	(0.3)	0	(0.0)
Hepatobiliary disorders	**4**	**(0.9)**	**4**	**(0.9)**	**19**	**(1.2)**	**13**	**(0.8)**
Autoimmune hepatitis	2	(0.4)	2	(0.4)	9	(0.6)	7	(0.4)
Cholestasis	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Drug-induced liver injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Hepatitis	1	(0.2)	1	(0.2)	5	(0.3)	4	(0.3)
Hyperbilirubinaemia	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Immune system disorders	**5**	**(1.1)**	**1**	**(0.2)**	**18**	**(1.1)**	**3**	**(0.2)**
Allergy to animal	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Atopy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Autoimmune disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cytokine release syndrome	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Drug hypersensitivity	1	(0.2)	1	(0.2)	3	(0.2)	1	(0.1)
Hypersensitivity	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Sarcoidosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Seasonal allergy	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Infections and infestations	**29**	**(6.3)**	**3**	**(0.7)**	**67**	**(4.3)**	**7**	**(0.4)**
Bacterial sepsis	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Candida infection	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Clostridium difficile infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Conjunctivitis	5	(1.1)	0	(0.0)	10	(0.6)	0	(0.0)
Diverticulitis	1	(0.2)	0	(0.0)	3	(0.2)	1	(0.1)
Encephalitis	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Erysipelas	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Folliculitis	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Fungal skin infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastroenteritis viral	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Herpes zoster	3	(0.7)	0	(0.0)	4	(0.3)	0	(0.0)
Hordeolum	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Influenza	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Lung infection	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Lymph gland infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nasopharyngitis	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Oral candidiasis	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Oral fungal infection	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oral herpes	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Otitis media	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pharyngitis	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pneumonia	1	(0.2)	1	(0.2)	3	(0.2)	1	(0.1)
Respiratory tract infection	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Rhinitis	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Sinusitis	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)
Skin infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Staphylococcal infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tinea versicolour	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tooth abscess	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tuberculosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Upper respiratory tract infection	4	(0.9)	0	(0.0)	4	(0.3)	0	(0.0)
Urinary tract infection	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Injury, poisoning and procedural complications	**4**	**(0.9)**	**0**	**(0.0)**	**20**	**(1.3)**	**0**	**(0.0)**
Chillblains	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Contusion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Excoriation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Incision site complication	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Infusion related reaction	3	(0.7)	0	(0.0)	12	(0.8)	0	(0.0)
Procedural pain	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Radiation skin injury	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sunburn	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Tooth fracture	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Investigations	**67**	**(14.6)**	**4**	**(0.9)**	**201**	**(12.8)**	**17**	**(1.1)**
Activated partial thromboplastin time prolonged	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Alanine aminotransferase	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Alanine aminotransferase increased	20	(4.4)	0	(0.0)	52	(3.3)	3	(0.2)
Amylase increased	1	(0.2)	0	(0.0)	4	(0.3)	1	(0.1)
Aortic bruit	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aspartate aminotransferase increased	22	(4.8)	0	(0.0)	52	(3.3)	5	(0.3)
Autoantibody positive	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bilirubin conjugated increased	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood alkaline phosphatase decreased	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood alkaline phosphatase increased	6	(1.3)	0	(0.0)	15	(1.0)	0	(0.0)
Blood bicarbonate decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood bilirubin increased	10	(2.2)	0	(0.0)	16	(1.0)	0	(0.0)
Blood calcium increased	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Blood cholesterol increased	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Blood corticotrophin decreased	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Blood corticotrophin increased	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood cortisol decreased	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Blood creatine phosphokinase increased	1	(0.2)	0	(0.0)	4	(0.3)	2	(0.1)
Blood creatinine increased	8	(1.7)	0	(0.0)	16	(1.0)	0	(0.0)
Blood glucose abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood glucose increased	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)
Blood lactate dehydrogenase increased	5	(1.1)	1	(0.2)	5	(0.3)	1	(0.1)
Blood luteinising hormone decreased	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood parathyroid hormone increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood phosphorus decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood testosterone decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood thyroid stimulating hormone decreased	3	(0.7)	0	(0.0)	13	(0.8)	0	(0.0)
Blood thyroid stimulating hormone increased	2	(0.4)	0	(0.0)	11	(0.7)	0	(0.0)
Blood triglycerides increased	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Blood urea increased	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Body temperature increased	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
C-reactive protein increased	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Electrocardiogram QT prolonged	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Electrocardiogram repolarisation abnormality	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eosinophil count increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gamma-glutamyltransferase increased	3	(0.7)	1	(0.2)	8	(0.5)	4	(0.3)
Haemoglobin decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hepatic enzyme increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lipase	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lipase increased	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Liver function test abnormal	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Lymphocyte count decreased	3	(0.7)	0	(0.0)	11	(0.7)	2	(0.1)
Neutrophil count decreased	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Neutrophil count increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Platelet count decreased	3	(0.7)	0	(0.0)	8	(0.5)	0	(0.0)
Thyroglobulin increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroxine decreased	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Thyroxine free increased	1	(0.2)	0	(0.0)	4	(0.3)	0	(0.0)
Thyroxine increased	2	(0.4)	0	(0.0)	4	(0.3)	0	(0.0)
Transaminases increased	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Tri-iodothyronine decreased	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Tri-iodothyronine increased	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Weight decreased	7	(1.5)	0	(0.0)	26	(1.7)	0	(0.0)
Weight increased	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
White blood cell count decreased	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
White blood cell count increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Metabolism and nutrition disorders	**60**	**(13.1)**	**10**	**(2.2)**	**182**	**(11.6)**	**24**	**(1.5)**
Cell death	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Decreased appetite	39	(8.5)	1	(0.2)	116	(7.4)	3	(0.2)
Dehydration	5	(1.1)	1	(0.2)	13	(0.8)	2	(0.1)
Diabetes mellitus	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Electrolyte imbalance	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Failure to thrive	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Fluid overload	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Fluid retention	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Gout	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypercalcaemia	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Hypercholesterolaemia	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Hyperglycaemia	2	(0.4)	1	(0.2)	8	(0.5)	2	(0.1)
Hyperkalaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperlipidaemia	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hypertriglyceridaemia	2	(0.4)	1	(0.2)	8	(0.5)	1	(0.1)
Hyperuricaemia	1	(0.2)	0	(0.0)	4	(0.3)	0	(0.0)
Hypoalbuminaemia	2	(0.4)	1	(0.2)	4	(0.3)	2	(0.1)
Hypocalcaemia	6	(1.3)	0	(0.0)	14	(0.9)	0	(0.0)
Hypokalaemia	4	(0.9)	4	(0.9)	12	(0.8)	6	(0.4)
Hypomagnesaemia	4	(0.9)	0	(0.0)	9	(0.6)	0	(0.0)
Hyponatraemia	1	(0.2)	1	(0.2)	8	(0.5)	6	(0.4)
Hypophosphataemia	3	(0.7)	1	(0.2)	10	(0.6)	1	(0.1)
Increased appetite	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Insulin resistant diabetes	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Iron deficiency	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Vitamin B12 deficiency	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Musculoskeletal and connective tissue disorders	**116**	**(25.3)**	**3**	**(0.7)**	**346**	**(22.1)**	**12**	**(0.8)**
Ankylosing spondylitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Arthralgia	56	(12.2)	0	(0.0)	190	(12.1)	3	(0.2)
Arthritis	10	(2.2)	0	(0.0)	16	(1.0)	0	(0.0)
Arthropathy	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Back pain	11	(2.4)	0	(0.0)	30	(1.9)	0	(0.0)
Bone pain	4	(0.9)	0	(0.0)	7	(0.4)	0	(0.0)
Chondrocalcinosis pyrophosphate	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Fibromyalgia	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Flank pain	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Groin pain	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Growing pains	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Joint effusion	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Joint range of motion decreased	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Joint stiffness	2	(0.4)	0	(0.0)	9	(0.6)	0	(0.0)
Joint swelling	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Limb discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle atrophy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle spasms	7	(1.5)	0	(0.0)	22	(1.4)	0	(0.0)
Muscle tightness	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle twitching	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Muscular weakness	3	(0.7)	0	(0.0)	20	(1.3)	2	(0.1)
Musculoskeletal chest pain	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Musculoskeletal discomfort	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Musculoskeletal pain	4	(0.9)	0	(0.0)	14	(0.9)	1	(0.1)
Musculoskeletal stiffness	6	(1.3)	0	(0.0)	19	(1.2)	0	(0.0)
Myalgia	43	(9.4)	1	(0.2)	101	(6.4)	3	(0.2)
Myopathy	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Myositis	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Neck pain	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Nodal osteoarthritis	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Osteoarthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pain in extremity	15	(3.3)	1	(0.2)	30	(1.9)	2	(0.1)
Pain in jaw	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Plantar fasciitis	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Polyarthritis	3	(0.7)	0	(0.0)	4	(0.3)	0	(0.0)
Polymyalgia rheumatica	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sjogren's syndrome	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Synovitis	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Tendon pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tendonitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tenosynovitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Torticollis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**5**	**(1.1)**	**0**	**(0.0)**	**17**	**(1.1)**	**0**	**(0.0)**
Acrochordon	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Infected neoplasm	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Keratoacanthoma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Malignant melanoma	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Melanocytic naevus	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Metastatic pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neoplasm swelling	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oncologic complication	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Seborrhoeic keratosis	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Skin papilloma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tumour pain	0	(0.0)	0	(0.0)	6	(0.4)	0	(0.0)
Nervous system disorders	**72**	**(15.7)**	**3**	**(0.7)**	**205**	**(13.1)**	**10**	**(0.6)**
Ageusia	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Amnesia	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Amnestic disorder	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Balance disorder	3	(0.7)	0	(0.0)	3	(0.2)	0	(0.0)
Brain oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Carpal tunnel syndrome	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cognitive disorder	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Convulsion	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Depressed level of consciousness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Disturbance in attention	2	(0.4)	0	(0.0)	4	(0.3)	0	(0.0)
Dizziness	16	(3.5)	0	(0.0)	25	(1.6)	0	(0.0)
Dysaesthesia	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Dysarthria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dysgeusia	11	(2.4)	0	(0.0)	31	(2.0)	0	(0.0)
Encephalopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Epilepsy	2	(0.4)	2	(0.4)	3	(0.2)	3	(0.2)
Guillain-Barre syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Haemorrhagic stroke	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Headache	27	(5.9)	0	(0.0)	78	(5.0)	2	(0.1)
Hyperaesthesia	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hypersomnia	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hypoaesthesia	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Hypogeusia	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Hypotonia	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Judgement impaired	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lethargy	2	(0.4)	0	(0.0)	10	(0.6)	0	(0.0)
Loss of consciousness	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Memory impairment	4	(0.9)	0	(0.0)	10	(0.6)	0	(0.0)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Neuralgia	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Neuropathy peripheral	6	(1.3)	0	(0.0)	15	(1.0)	0	(0.0)
Optic neuritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Paraesthesia	3	(0.7)	0	(0.0)	14	(0.9)	0	(0.0)
Parosmia	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Partial seizures	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral sensory neuropathy	2	(0.4)	0	(0.0)	4	(0.3)	0	(0.0)
Polyneuropathy	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Poor quality sleep	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Presyncope	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Restless legs syndrome	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Sciatica	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sensory disturbance	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Syncope	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tremor	0	(0.0)	0	(0.0)	4	(0.3)	0	(0.0)
Psychiatric disorders	**18**	**(3.9)**	**0**	**(0.0)**	**44**	**(2.8)**	**1**	**(0.1)**
Affective disorder	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Agitation	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Anxiety	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Confusional state	4	(0.9)	0	(0.0)	8	(0.5)	1	(0.1)
Depression	4	(0.9)	0	(0.0)	5	(0.3)	0	(0.0)
Disorientation	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Dysphoria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hallucination	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Insomnia	8	(1.7)	0	(0.0)	16	(1.0)	0	(0.0)
Irritability	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Libido decreased	0	(0.0)	0	(0.0)	4	(0.3)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Middle insomnia	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Phobia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sleep disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Trance	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Renal and urinary disorders	**11**	**(2.4)**	**3**	**(0.7)**	**23**	**(1.5)**	**4**	**(0.3)**
Chromaturia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dysuria	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Haematuria	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Pollakiuria	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Proteinuria	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Renal failure	2	(0.4)	1	(0.2)	5	(0.3)	2	(0.1)
Renal failure acute	2	(0.4)	2	(0.4)	4	(0.3)	2	(0.1)
Renal failure chronic	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Renal impairment	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tubulointerstitial nephritis	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Urinary incontinence	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Urine odour abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Reproductive system and breast disorders	**5**	**(1.1)**	**0**	**(0.0)**	**19**	**(1.2)**	**1**	**(0.1)**
Amenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Breast pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Breast tenderness	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dysmenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erectile dysfunction	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Genital rash	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haematospermia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Menorrhagia	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Nipple pain	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Nipple swelling	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pelvic pain	0	(0.0)	0	(0.0)	4	(0.3)	1	(0.1)
Pruritus genital	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Scrotal erythema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vulvovaginal pruritus	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**54**	**(11.8)**	**3**	**(0.7)**	**193**	**(12.3)**	**15**	**(1.0)**
Asthma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Bronchial hyperreactivity	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Cough	21	(4.6)	1	(0.2)	82	(5.2)	1	(0.1)
Dysphonia	1	(0.2)	0	(0.0)	3	(0.2)	1	(0.1)
Dyspnoea	16	(3.5)	0	(0.0)	65	(4.1)	6	(0.4)
Dyspnoea exertional	4	(0.9)	0	(0.0)	12	(0.8)	0	(0.0)
Epistaxis	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Haemoptysis	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hiccups	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Interstitial lung disease	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Laryngeal discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Laryngeal inflammation	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Nasal congestion	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Nasal dryness	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nasal mucosal disorder	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oropharyngeal pain	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Painful respiration	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Pleural effusion	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Pleuritic pain	2	(0.4)	1	(0.2)	3	(0.2)	1	(0.1)
Pneumonitis	8	(1.7)	1	(0.2)	26	(1.7)	5	(0.3)
Productive cough	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Pulmonary congestion	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pulmonary oedema	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Respiratory failure	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rhinitis allergic	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Rhinorrhoea	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Sinus congestion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sneezing	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Throat irritation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Wheezing	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Skin and subcutaneous tissue disorders	**209**	**(45.6)**	**7**	**(1.5)**	**703**	**(44.9)**	**16**	**(1.0)**
Acne	2	(0.4)	0	(0.0)	4	(0.3)	0	(0.0)
Actinic keratosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Alopecia	4	(0.9)	0	(0.0)	16	(1.0)	0	(0.0)
Blister	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Dermatitis acneiform	1	(0.2)	0	(0.0)	10	(0.6)	0	(0.0)
Dermatitis allergic	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis contact	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis exfoliative	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis psoriasiform	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Drug eruption	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dry skin	10	(2.2)	0	(0.0)	47	(3.0)	0	(0.0)
Eczema	7	(1.5)	0	(0.0)	22	(1.4)	0	(0.0)
Eczema asteatotic	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erythema	12	(2.6)	0	(0.0)	37	(2.4)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Erythema nodosum	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Exfoliative rash	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Granuloma skin	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hair colour changes	8	(1.7)	0	(0.0)	15	(1.0)	0	(0.0)
Hair growth abnormal	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Hair texture abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperhidrosis	5	(1.1)	0	(0.0)	13	(0.8)	0	(0.0)
Hyperkeratosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypertrichosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ichthyosis acquired	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Keratosis pilaris	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Lichen planus	2	(0.4)	1	(0.2)	2	(0.1)	1	(0.1)
Lichen sclerosus	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lichenoid keratosis	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Linear IgA disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Macule	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Madarosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nail discolouration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nail disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nail growth abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Neutrophilic dermatosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Night sweats	9	(2.0)	0	(0.0)	27	(1.7)	0	(0.0)
Onychoclasis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pain of skin	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Panniculitis	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Papule	4	(0.9)	0	(0.0)	10	(0.6)	0	(0.0)
Parapsoriasis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pemphigoid	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Photosensitivity reaction	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Pigmentation disorder	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Prurigo	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Pruritus	84	(18.3)	1	(0.2)	320	(20.4)	2	(0.1)
Pruritus generalised	4	(0.9)	0	(0.0)	15	(1.0)	0	(0.0)
Psoriasis	3	(0.7)	1	(0.2)	6	(0.4)	1	(0.1)
Purpura	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pustular psoriasis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rash	74	(16.2)	1	(0.2)	249	(15.9)	2	(0.1)
Rash erythematous	6	(1.3)	1	(0.2)	10	(0.6)	1	(0.1)
Rash follicular	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Rash generalised	4	(0.9)	0	(0.0)	13	(0.8)	1	(0.1)
Rash macular	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Rash maculo-papular	14	(3.1)	0	(0.0)	51	(3.3)	4	(0.3)
Rash papular	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Rash pruritic	8	(1.7)	1	(0.2)	17	(1.1)	1	(0.1)
Rash vesicular	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Rosacea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Scab	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sebaceous gland disorder	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Seborrhoeic dermatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin burning sensation	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Skin depigmentation	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Skin discolouration	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Skin disorder	0	(0.0)	0	(0.0)	4	(0.3)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Skin exfoliation	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Skin haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Skin hyperpigmentation	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Skin hypopigmentation	7	(1.5)	0	(0.0)	25	(1.6)	0	(0.0)
Skin irritation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin lesion	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Skin mass	1	(0.2)	0	(0.0)	4	(0.3)	0	(0.0)
Skin ulcer	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Solar dermatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Stevens-Johnson syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Transient acantholytic dermatosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Urticaria	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Urticaria papular	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Vitiligo	49	(10.7)	0	(0.0)	144	(9.2)	0	(0.0)
Xanthelasma	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Xeroderma	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Vascular disorders	**19**	**(4.1)**	**2**	**(0.4)**	**46**	**(2.9)**	**4**	**(0.3)**
Flushing	4	(0.9)	0	(0.0)	10	(0.6)	0	(0.0)
Haematoma	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hot flush	6	(1.3)	0	(0.0)	15	(1.0)	0	(0.0)
Hypertension	3	(0.7)	2	(0.4)	5	(0.3)	3	(0.2)
Hypotension	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Intermittent claudication	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Jugular vein thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphoedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pallor	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral coldness	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral ischaemia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Raynaud's phenomenon	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Varicophlebitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vasculitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-13 副作用（いずれかの投与群で発現割合 0%超）
001 試験+002 試験+006 試験（APaT 集団）（続き）

	MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)
Venous thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

Every subject is counted a single time for each applicable row and column.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.

MedDRA preferred terms 'Malignant Neoplasm Progression' not related to the drug is excluded.

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付録 2.7.4-14 有害事象（発現割合 0%超）
041 試験（APaT 集団）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Subjects in population	42			
with one or more adverse events	41	(97.6)	17	(40.5)
with no adverse events	1	(2.4)	25	(59.5)
Blood and lymphatic system disorders	**4**	**(9.5)**	**4**	**(9.5)**
Anaemia	4	(9.5)	4	(9.5)
Coagulopathy	1	(2.4)	0	(0.0)
Lymphopenia	2	(4.8)	1	(2.4)
Ear and labyrinth disorders	**1**	**(2.4)**	**0**	**(0.0)**
Meniere's disease	1	(2.4)	0	(0.0)
Vertigo	1	(2.4)	0	(0.0)
Endocrine disorders	**10**	**(23.8)**	**1**	**(2.4)**
Hyperthyroidism	2	(4.8)	0	(0.0)
Hypophysitis	2	(4.8)	1	(2.4)
Hypopituitarism	1	(2.4)	0	(0.0)
Hypothyroidism	5	(11.9)	0	(0.0)
Eye disorders	**5**	**(11.9)**	**0**	**(0.0)**
Cataract	1	(2.4)	0	(0.0)
Diplopia	1	(2.4)	0	(0.0)
Dry eye	1	(2.4)	0	(0.0)
Keratitis	1	(2.4)	0	(0.0)
Photopsia	1	(2.4)	0	(0.0)
Uveitis	1	(2.4)	0	(0.0)
Vision blurred	1	(2.4)	0	(0.0)
Gastrointestinal disorders	**25**	**(59.5)**	**3**	**(7.1)**
Abdominal pain	2	(4.8)	0	(0.0)
Abdominal pain upper	3	(7.1)	0	(0.0)
Cheilitis	3	(7.1)	0	(0.0)
Colitis	2	(4.8)	1	(2.4)
Constipation	9	(21.4)	0	(0.0)
Dental caries	2	(4.8)	0	(0.0)
Diarrhoea	6	(14.3)	0	(0.0)
Dry mouth	2	(4.8)	0	(0.0)
Duodenal ulcer haemorrhage	1	(2.4)	1	(2.4)
Gastritis	1	(2.4)	0	(0.0)
Gastrointestinal ulcer	1	(2.4)	0	(0.0)
Gastrooesophageal reflux disease	1	(2.4)	0	(0.0)

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付録 2.7.4-14 有害事象（発現割合 0%超）

041 試験（APaT 集団）（続き）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Gastrointestinal disorders	**25**	**(59.5)**	**3**	**(7.1)**
Haemorrhoids	1	(2.4)	0	(0.0)
Large intestinal obstruction	1	(2.4)	0	(0.0)
Nausea	7	(16.7)	1	(2.4)
Stomatitis	2	(4.8)	0	(0.0)
Vomiting	4	(9.5)	0	(0.0)
General disorders and administration site conditions	**13**	**(31.0)**	**1**	**(2.4)**
Chest discomfort	1	(2.4)	0	(0.0)
Chest pain	2	(4.8)	0	(0.0)
Death	1	(2.4)	1	(2.4)
Fatigue	1	(2.4)	0	(0.0)
Influenza like illness	2	(4.8)	0	(0.0)
Malaise	6	(14.3)	0	(0.0)
Oedema peripheral	1	(2.4)	0	(0.0)
Pyrexia	5	(11.9)	0	(0.0)
Thirst	1	(2.4)	0	(0.0)
Hepatobiliary disorders	**2**	**(4.8)**	**1**	**(2.4)**
Bile duct obstruction	1	(2.4)	1	(2.4)
Hepatic function abnormal	1	(2.4)	0	(0.0)
Immune system disorders	**1**	**(2.4)**	**0**	**(0.0)**
Cytokine release syndrome	1	(2.4)	0	(0.0)
Infections and infestations	**24**	**(57.1)**	**4**	**(9.5)**
Cellulitis	2	(4.8)	1	(2.4)
Cystitis	1	(2.4)	0	(0.0)
Gastroenteritis	1	(2.4)	0	(0.0)
Helicobacter infection	1	(2.4)	0	(0.0)
Herpes simplex	1	(2.4)	0	(0.0)
Infected dermal cyst	1	(2.4)	0	(0.0)
Infection	1	(2.4)	1	(2.4)
Influenza	3	(7.1)	0	(0.0)
Lung infection	1	(2.4)	0	(0.0)
Nasopharyngitis	11	(26.2)	0	(0.0)
Onychomycosis	1	(2.4)	0	(0.0)
Oral candidiasis	1	(2.4)	0	(0.0)
Pharyngitis	2	(4.8)	1	(2.4)
Rhinitis	1	(2.4)	0	(0.0)

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付録 2.7.4-14 有害事象（発現割合 0%超）
041 試験（APaT 集団）（続き）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Infections and infestations	**24**	**(57.1)**	**4**	**(9.5)**
Sinusitis	1	(2.4)	0	(0.0)
Vestibular neuronitis	1	(2.4)	1	(2.4)
Viral pharyngitis	1	(2.4)	0	(0.0)
Vulvitis	1	(2.4)	0	(0.0)
Injury, poisoning and procedural complications	**5**	**(11.9)**	**0**	**(0.0)**
Arthropod sting	2	(4.8)	0	(0.0)
Fracture	1	(2.4)	0	(0.0)
Infusion related reaction	1	(2.4)	0	(0.0)
Radiation skin injury	1	(2.4)	0	(0.0)
Skin abrasion	1	(2.4)	0	(0.0)
Investigations	**17**	**(40.5)**	**3**	**(7.1)**
Alanine aminotransferase increased	2	(4.8)	0	(0.0)
Aspartate aminotransferase increased	3	(7.1)	0	(0.0)
Blood creatine phosphokinase increased	1	(2.4)	0	(0.0)
Blood creatinine increased	1	(2.4)	0	(0.0)
Blood magnesium increased	1	(2.4)	0	(0.0)
Blood thyroid stimulating hormone decreased	1	(2.4)	0	(0.0)
Blood thyroid stimulating hormone increased	1	(2.4)	0	(0.0)
Blood urine	1	(2.4)	0	(0.0)
Eosinophil count increased	3	(7.1)	0	(0.0)
Lymphocyte count decreased	2	(4.8)	2	(4.8)
Thyroid function test abnormal	1	(2.4)	0	(0.0)
Weight decreased	4	(9.5)	1	(2.4)
Weight increased	2	(4.8)	0	(0.0)
White blood cell count decreased	2	(4.8)	0	(0.0)
Metabolism and nutrition disorders	**15**	**(35.7)**	**6**	**(14.3)**
Alcohol intolerance	1	(2.4)	0	(0.0)
Decreased appetite	5	(11.9)	1	(2.4)
Dehydration	1	(2.4)	0	(0.0)
Diabetes mellitus	1	(2.4)	1	(2.4)
Hyperglycaemia	1	(2.4)	1	(2.4)
Hyperkalaemia	1	(2.4)	0	(0.0)
Hypertriglyceridaemia	1	(2.4)	1	(2.4)
Hyperuricaemia	2	(4.8)	0	(0.0)

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付録 2.7.4-14 有害事象（発現割合 0%超）

041 試験（APaT 集団）（続き）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Metabolism and nutrition disorders	**15**	**(35.7)**	**6**	**(14.3)**
Hyponatraemia	2	(4.8)	2	(4.8)
Marasmus	1	(2.4)	0	(0.0)
Musculoskeletal and connective tissue disorders	**6**	**(14.3)**	**0**	**(0.0)**
Arthralgia	1	(2.4)	0	(0.0)
Arthritis	1	(2.4)	0	(0.0)
Back pain	1	(2.4)	0	(0.0)
Ligamentitis	1	(2.4)	0	(0.0)
Musculoskeletal pain	2	(4.8)	0	(0.0)
Osteoarthritis	1	(2.4)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**2**	**(4.8)**	**1**	**(2.4)**
Cancer pain	2	(4.8)	1	(2.4)
Nervous system disorders	**5**	**(11.9)**	**1**	**(2.4)**
Cerebral haemorrhage	1	(2.4)	1	(2.4)
Dizziness	2	(4.8)	0	(0.0)
Dysgeusia	2	(4.8)	0	(0.0)
Encephalopathy	1	(2.4)	1	(2.4)
Headache	1	(2.4)	0	(0.0)
Presyncope	1	(2.4)	0	(0.0)
Psychiatric disorders	**3**	**(7.1)**	**1**	**(2.4)**
Insomnia	3	(7.1)	1	(2.4)
Reproductive system and breast disorders	**3**	**(7.1)**	**0**	**(0.0)**
Genital haemorrhage	1	(2.4)	0	(0.0)
Metrorrhagia	1	(2.4)	0	(0.0)
Prostatic obstruction	1	(2.4)	0	(0.0)
Vulvar erosion	1	(2.4)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**17**	**(40.5)**	**3**	**(7.1)**
Acute respiratory failure	1	(2.4)	1	(2.4)
Cough	3	(7.1)	0	(0.0)
Dysphonia	1	(2.4)	0	(0.0)
Dyspnoea	2	(4.8)	1	(2.4)

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付録 2.7.4-14 有害事象（発現割合 0%超）

041 試験（APaT 集団）（続き）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**17**	**(40.5)**	**3**	**(7.1)**
Epistaxis	3	(7.1)	1	(2.4)
Hiccups	2	(4.8)	0	(0.0)
Oropharyngeal pain	2	(4.8)	0	(0.0)
Pneumonia aspiration	1	(2.4)	0	(0.0)
Pneumonitis	1	(2.4)	0	(0.0)
Rhinitis allergic	3	(7.1)	0	(0.0)
Sleep apnoea syndrome	1	(2.4)	0	(0.0)
Skin and subcutaneous tissue disorders	**28**	**(66.7)**	**1**	**(2.4)**
Acne	1	(2.4)	0	(0.0)
Alopecia	1	(2.4)	0	(0.0)
Angioedema	1	(2.4)	0	(0.0)
Decubitus ulcer	1	(2.4)	0	(0.0)
Dermatitis	1	(2.4)	0	(0.0)
Dermatitis contact	1	(2.4)	0	(0.0)
Drug eruption	1	(2.4)	1	(2.4)
Dry skin	5	(11.9)	0	(0.0)
Eczema	2	(4.8)	0	(0.0)
Eczema asteatotic	2	(4.8)	0	(0.0)
Miliaria	3	(7.1)	0	(0.0)
Papule	1	(2.4)	0	(0.0)
Pruritus	10	(23.8)	0	(0.0)
Purpura	1	(2.4)	0	(0.0)
Rash	2	(4.8)	0	(0.0)
Rash maculo-papular	7	(16.7)	0	(0.0)
Seborrhoeic dermatitis	2	(4.8)	0	(0.0)
Skin hypopigmentation	2	(4.8)	0	(0.0)
Skin induration	1	(2.4)	0	(0.0)
Skin mass	1	(2.4)	0	(0.0)
Toxic skin eruption	1	(2.4)	0	(0.0)
Urticaria	1	(2.4)	0	(0.0)
Vitiligo	3	(7.1)	0	(0.0)
Vascular disorders	**2**	**(4.8)**	**0**	**(0.0)**

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付録 2.7.4-14 有害事象（発現割合 0%超）

041 試験（APaT 集団）（続き）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Vascular disorders	**2**	**(4.8)**	**0**	**(0.0)**
Hypertension	2	(4.8)	0	(0.0)

Every subject is counted a single time for each applicable row and column.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.

Grades are based on NCI CTCAE version 4.0.

MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.

Adverse event terms are from MedDRA Version 18.0.

(Database Cutoff Date: [redacted]

Data Source: [資料5.3.5.2.3: P041V01]

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	382				769				458				1,609			
with one or more adverse events	374	(97.9)	165	(43.2)	747	(97.1)	298	(38.8)	453	(98.9)	186	(40.6)	1,574	(97.8)	649	(40.3)
with no adverse events	8	(2.1)	217	(56.8)	22	(2.9)	471	(61.2)	5	(1.1)	272	(59.4)	35	(2.2)	960	(59.7)
Blood and lymphatic system disorders	**72**	**(18.8)**	**30**	**(7.9)**	**131**	**(17.0)**	**24**	**(3.1)**	**73**	**(15.9)**	**26**	**(5.7)**	**276**	**(17.2)**	**80**	**(5.0)**
Anaemia	62	(16.2)	28	(7.3)	88	(11.4)	20	(2.6)	52	(11.4)	18	(3.9)	202	(12.6)	66	(4.1)
Anaemia of chronic disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Coagulopathy	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Disseminated intravascular coagulation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Eosinophilia	2	(0.5)	0	(0.0)	8	(1.0)	0	(0.0)	2	(0.4)	0	(0.0)	12	(0.7)	0	(0.0)
Haemolytic anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Haemorrhagic diathesis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Immune thrombocytopenic purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Blood and lymphatic system disorders	**72**	**(18.8)**	**30**	**(7.9)**	**131**	**(17.0)**	**24**	**(3.1)**	**73**	**(15.9)**	**26**	**(5.7)**	**276**	**(17.2)**	**80**	**(5.0)**
Increased tendency to bruise	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Iron deficiency anaemia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Leukocytosis	3	(0.8)	1	(0.3)	8	(1.0)	0	(0.0)	5	(1.1)	1	(0.2)	16	(1.0)	2	(0.1)
Leukopenia	1	(0.3)	0	(0.0)	5	(0.7)	1	(0.1)	4	(0.9)	0	(0.0)	10	(0.6)	1	(0.1)
Lymph node pain	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Lymphadenitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Lymphadenopathy	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	7	(0.4)	0	(0.0)
Lymphatic obstruction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphopenia	3	(0.8)	1	(0.3)	9	(1.2)	1	(0.1)	4	(0.9)	3	(0.7)	16	(1.0)	5	(0.3)
Microcytic anaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neutropenia	2	(0.5)	1	(0.3)	4	(0.5)	1	(0.1)	4	(0.9)	1	(0.2)	10	(0.6)	3	(0.2)
Pancytopenia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Polycythaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Splenic infarction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Thrombocytopenia	8	(2.1)	1	(0.3)	11	(1.4)	2	(0.3)	10	(2.2)	1	(0.2)	29	(1.8)	4	(0.2)
Thrombocytosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Cardiac disorders	**27**	**(7.1)**	**7**	**(1.8)**	**60**	**(7.8)**	**15**	**(2.0)**	**42**	**(9.2)**	**10**	**(2.2)**	**129**	**(8.0)**	**32**	**(2.0)**

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**27**	**(7.1)**	**7**	**(1.8)**	**60**	**(7.8)**	**15**	**(2.0)**	**42**	**(9.2)**	**10**	**(2.2)**	**129**	**(8.0)**	**32**	**(2.0)**
Acute coronary syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Acute myocardial infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.4)	2	(0.4)	3	(0.2)	3	(0.2)
Angina pectoris	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Angina unstable	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aortic valve incompetence	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aortic valve stenosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Arrhythmia supraventricular	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Atrial fibrillation	3	(0.8)	1	(0.3)	8	(1.0)	3	(0.4)	6	(1.3)	3	(0.7)	17	(1.1)	7	(0.4)
Atrial flutter	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	4	(0.2)	1	(0.1)
Atrial thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Atrioventricular block first degree	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bradycardia	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	3	(0.7)	0	(0.0)	8	(0.5)	0	(0.0)
Bundle branch block left	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Bundle branch block right	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Cardiac aneurysm	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cardiac arrest	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**27**	**(7.1)**	**7**	**(1.8)**	**60**	**(7.8)**	**15**	**(2.0)**	**42**	**(9.2)**	**10**	**(2.2)**	**129**	**(8.0)**	**32**	**(2.0)**
Cardiac disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cardiac failure	0	(0.0)	0	(0.0)	3	(0.4)	2	(0.3)	3	(0.7)	3	(0.7)	6	(0.4)	5	(0.3)
Cardiac failure congestive	1	(0.3)	1	(0.3)	4	(0.5)	3	(0.4)	2	(0.4)	1	(0.2)	7	(0.4)	5	(0.3)
Cardiac ventricular disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Cardiac ventricular thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cardiogenic shock	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cardiomegaly	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Congestive cardiomyopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Coronary artery disease	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Cyanosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Left ventricular dysfunction	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Left ventricular hypertrophy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Mitral valve incompetence	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Myocardial infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	1	(0.2)	2	(0.1)	2	(0.1)
Palpitations	6	(1.6)	0	(0.0)	9	(1.2)	0	(0.0)	5	(1.1)	0	(0.0)	20	(1.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Cardiac disorders	**27**	**(7.1)**	**7**	**(1.8)**	**60**	**(7.8)**	**15**	**(2.0)**	**42**	**(9.2)**	**10**	**(2.2)**	**129**	**(8.0)**	**32**	**(2.0)**
Pericardial effusion	4	(1.0)	2	(0.5)	2	(0.3)	1	(0.1)	5	(1.1)	1	(0.2)	11	(0.7)	4	(0.2)
Pericarditis	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Sinus bradycardia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	4	(0.9)	0	(0.0)	5	(0.3)	0	(0.0)
Sinus tachycardia	2	(0.5)	1	(0.3)	5	(0.7)	0	(0.0)	3	(0.7)	0	(0.0)	10	(0.6)	1	(0.1)
Supraventricular tachycardia	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	4	(0.9)	1	(0.2)	6	(0.4)	2	(0.1)
Tachycardia	5	(1.3)	0	(0.0)	16	(2.1)	0	(0.0)	9	(2.0)	1	(0.2)	30	(1.9)	1	(0.1)
Ventricular extrasystoles	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Congenital, familial and genetic disorders	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(0.4)**	**0**	**(0.0)**	**2**	**(0.1)**	**0**	**(0.0)**
Accessory spleen	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Naevus flammeus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Ear and labyrinth disorders	**24**	**(6.3)**	**1**	**(0.3)**	**41**	**(5.3)**	**0**	**(0.0)**	**23**	**(5.0)**	**1**	**(0.2)**	**88**	**(5.5)**	**2**	**(0.1)**
Cerumen impaction	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Deafness	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	4	(0.9)	1	(0.2)	7	(0.4)	1	(0.1)
Deafness unilateral	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Ear discomfort	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Ear haemorrhage	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Ear pain	6	(1.6)	0	(0.0)	12	(1.6)	0	(0.0)	2	(0.4)	0	(0.0)	20	(1.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Ear and labyrinth disorders	**24**	**(6.3)**	**1**	**(0.3)**	**41**	**(5.3)**	**0**	**(0.0)**	**23**	**(5.0)**	**1**	**(0.2)**	**88**	**(5.5)**	**2**	**(0.1)**
Ear swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
External ear inflammation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
External ear pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Hearing impaired	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Hypoacusis	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Meniere's disease	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Middle ear inflammation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Motion sickness	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tinnitus	1	(0.3)	0	(0.0)	7	(0.9)	0	(0.0)	2	(0.4)	0	(0.0)	10	(0.6)	0	(0.0)
Vertigo	7	(1.8)	0	(0.0)	17	(2.2)	0	(0.0)	6	(1.3)	0	(0.0)	30	(1.9)	0	(0.0)
Vertigo positional	2	(0.5)	1	(0.3)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	1	(0.1)
Endocrine disorders	**49**	**(12.8)**	**5**	**(1.3)**	**83**	**(10.8)**	**7**	**(0.9)**	**62**	**(13.5)**	**6**	**(1.3)**	**194**	**(12.1)**	**18**	**(1.1)**
Adrenal insufficiency	1	(0.3)	1	(0.3)	5	(0.7)	2	(0.3)	3	(0.7)	2	(0.4)	9	(0.6)	5	(0.3)
Adrenocortical insufficiency acute	1	(0.3)	1	(0.3)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Endocrine disorders	**49**	**(12.8)**	**5**	**(1.3)**	**83**	**(10.8)**	**7**	**(0.9)**	**62**	**(13.5)**	**6**	**(1.3)**	**194**	**(12.1)**	**18**	**(1.1)**
Cushingoid	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Endocrine disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Goitre	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperparathyroidism	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Hyperthyroidism	11	(2.9)	0	(0.0)	18	(2.3)	1	(0.1)	24	(5.2)	1	(0.2)	53	(3.3)	2	(0.1)
Hypogonadism	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypoparathyroidism	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypophysitis	5	(1.3)	3	(0.8)	3	(0.4)	1	(0.1)	1	(0.2)	0	(0.0)	9	(0.6)	4	(0.2)
Hypopituitarism	3	(0.8)	0	(0.0)	2	(0.3)	2	(0.3)	2	(0.4)	1	(0.2)	7	(0.4)	3	(0.2)
Hypothyroidism	30	(7.9)	0	(0.0)	55	(7.2)	0	(0.0)	46	(10.0)	2	(0.4)	131	(8.1)	2	(0.1)
Primary hypothyroidism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroiditis	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Eye disorders	**57**	**(14.9)**	**2**	**(0.5)**	**97**	**(12.6)**	**4**	**(0.5)**	**67**	**(14.6)**	**1**	**(0.2)**	**221**	**(13.7)**	**7**	**(0.4)**
Abnormal sensation in eye	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Altered visual depth perception	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Asthenopia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Blindness	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**57**	**(14.9)**	**2**	**(0.5)**	**97**	**(12.6)**	**4**	**(0.5)**	**67**	**(14.6)**	**1**	**(0.2)**	**221**	**(13.7)**	**7**	**(0.4)**
Cataract	5	(1.3)	0	(0.0)	4	(0.5)	1	(0.1)	0	(0.0)	0	(0.0)	9	(0.6)	1	(0.1)
Chalazion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Ciliary muscle spasm	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Conjunctival haemorrhage	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Conjunctival hyperaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Conjunctivitis allergic	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Corneal pigmentation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Diplopia	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Dry age-related macular degeneration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dry eye	8	(2.1)	0	(0.0)	13	(1.7)	0	(0.0)	10	(2.2)	0	(0.0)	31	(1.9)	0	(0.0)
Ectropion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eczema eyelids	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Entropion	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Erythema of eyelid	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eye disorder	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Eye inflammation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eye irritation	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**57**	**(14.9)**	**2**	**(0.5)**	**97**	**(12.6)**	**4**	**(0.5)**	**67**	**(14.6)**	**1**	**(0.2)**	**221**	**(13.7)**	**7**	**(0.4)**
Eye movement disorder	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Eye pain	1	(0.3)	0	(0.0)	4	(0.5)	1	(0.1)	3	(0.7)	0	(0.0)	8	(0.5)	1	(0.1)
Eye pruritus	3	(0.8)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	8	(0.5)	0	(0.0)
Eye swelling	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Eyelash discolouration	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Eyelid disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelid exfoliation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelid function disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Eyelid oedema	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Eyelid ptosis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Eyelid rash	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelids pruritus	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Foreign body sensation in eyes	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Glaucoma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	1	(0.2)	2	(0.1)	1	(0.1)
Growth of eyelashes	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypermetropia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hypopigmentation of eyelid	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Iridocyclitis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**57**	**(14.9)**	**2**	**(0.5)**	**97**	**(12.6)**	**4**	**(0.5)**	**67**	**(14.6)**	**1**	**(0.2)**	**221**	**(13.7)**	**7**	**(0.4)**
Iritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)
Keratitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lacrimation increased	8	(2.1)	0	(0.0)	3	(0.4)	0	(0.0)	4	(0.9)	0	(0.0)	15	(0.9)	0	(0.0)
Macular degeneration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Ocular discomfort	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Ocular hyperaemia	2	(0.5)	0	(0.0)	5	(0.7)	0	(0.0)	2	(0.4)	0	(0.0)	9	(0.6)	0	(0.0)
Ophthalmoplegia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Optic neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Papilloedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Periorbital oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Photophobia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Photopsia	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Pupils unequal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Retinal detachment	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Retinal haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Retinal pigment epitheliopathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Retinal tear	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Retinal vein occlusion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Scleral hyperaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**57**	**(14.9)**	**2**	**(0.5)**	**97**	**(12.6)**	**4**	**(0.5)**	**67**	**(14.6)**	**1**	**(0.2)**	**221**	**(13.7)**	**7**	**(0.4)**
Scleritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Uveitis	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	1	(0.2)	0	(0.0)	9	(0.6)	0	(0.0)
Vision blurred	11	(2.9)	0	(0.0)	24	(3.1)	0	(0.0)	8	(1.7)	0	(0.0)	43	(2.7)	0	(0.0)
Visual acuity reduced	4	(1.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	8	(0.5)	0	(0.0)
Visual impairment	8	(2.1)	0	(0.0)	12	(1.6)	0	(0.0)	7	(1.5)	0	(0.0)	27	(1.7)	0	(0.0)
Vitreous detachment	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Vitreous floaters	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	4	(0.9)	0	(0.0)	8	(0.5)	0	(0.0)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Abdominal discomfort	6	(1.6)	0	(0.0)	16	(2.1)	0	(0.0)	9	(2.0)	0	(0.0)	31	(1.9)	0	(0.0)
Abdominal distension	14	(3.7)	0	(0.0)	26	(3.4)	0	(0.0)	14	(3.1)	1	(0.2)	54	(3.4)	1	(0.1)
Abdominal mass	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Abdominal pain	46	(12.0)	4	(1.0)	74	(9.6)	8	(1.0)	53	(11.6)	3	(0.7)	173	(10.8)	15	(0.9)
Abdominal pain lower	5	(1.3)	0	(0.0)	5	(0.7)	0	(0.0)	2	(0.4)	1	(0.2)	12	(0.7)	1	(0.1)
Abdominal pain upper	15	(3.9)	0	(0.0)	35	(4.6)	1	(0.1)	23	(5.0)	0	(0.0)	73	(4.5)	1	(0.1)
Abdominal rigidity	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Abdominal tenderness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Aerophagia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Anal fistula	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Anal pruritus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Anorectal disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Aphthous stomatitis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Aptyalism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Ascites	6	(1.6)	3	(0.8)	9	(1.2)	4	(0.5)	3	(0.7)	0	(0.0)	18	(1.1)	7	(0.4)
Auriculotemporal syndrome	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Autoimmune pancreatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Barrett's oesophagus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Breath odour	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Chapped lips	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cheilitis	6	(1.6)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	8	(0.5)	0	(0.0)
Chronic gastritis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Colitis	6	(1.6)	3	(0.8)	17	(2.2)	11	(1.4)	7	(1.5)	6	(1.3)	30	(1.9)	20	(1.2)
Colitis microscopic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Constipation	82	(21.5)	2	(0.5)	134	(17.4)	2	(0.3)	79	(17.2)	1	(0.2)	295	(18.3)	5	(0.3)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Defaecation urgency	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Dental caries	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Diarrhoea	89	(23.3)	4	(1.0)	189	(24.6)	8	(1.0)	139	(30.3)	12	(2.6)	417	(25.9)	24	(1.5)
Diverticulitis intestinal haemorrhagic	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Diverticulum	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	1	(0.2)	4	(0.2)	1	(0.1)
Dry mouth	13	(3.4)	0	(0.0)	40	(5.2)	0	(0.0)	41	(9.0)	0	(0.0)	94	(5.8)	0	(0.0)
Duodenal ulcer	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Duodenal ulcer haemorrhage	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Duodenitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Duodenogastric reflux	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dyspepsia	8	(2.1)	0	(0.0)	19	(2.5)	0	(0.0)	16	(3.5)	0	(0.0)	43	(2.7)	0	(0.0)
Dysphagia	10	(2.6)	1	(0.3)	8	(1.0)	0	(0.0)	8	(1.7)	1	(0.2)	26	(1.6)	2	(0.1)
Enteritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Enterocolitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Epigastric discomfort	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Eructation	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Faecal incontinence	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Faeces discoloured	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Faeces hard	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Faeces pale	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Faeces soft	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Femoral hernia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Flatulence	5	(1.3)	0	(0.0)	10	(1.3)	0	(0.0)	11	(2.4)	0	(0.0)	26	(1.6)	0	(0.0)
Food poisoning	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Frequent bowel movements	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Gastric disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Gastric ulcer haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Gastritis	3	(0.8)	1	(0.3)	5	(0.7)	2	(0.3)	3	(0.7)	0	(0.0)	11	(0.7)	3	(0.2)
Gastritis erosive	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrointestinal disorder	1	(0.3)	0	(0.0)	3	(0.4)	1	(0.1)	1	(0.2)	0	(0.0)	5	(0.3)	1	(0.1)
Gastrointestinal haemorrhage	0	(0.0)	0	(0.0)	3	(0.4)	2	(0.3)	2	(0.4)	2	(0.4)	5	(0.3)	4	(0.2)
Gastrointestinal pain	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	1	(0.1)
Gastrointestinal sounds abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Gastrointestinal ulcer	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Gastrooesophageal reflux disease	17	(4.5)	0	(0.0)	10	(1.3)	0	(0.0)	14	(3.1)	0	(0.0)	41	(2.5)	0	(0.0)
Gingival bleeding	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Gingival pain	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	7	(0.4)	0	(0.0)
Gingival swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Glossodynia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Haematemesis	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Haematochezia	6	(1.6)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	10	(0.6)	0	(0.0)
Haemorrhoidal haemorrhage	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Haemorrhoids	5	(1.3)	0	(0.0)	3	(0.4)	0	(0.0)	4	(0.9)	0	(0.0)	12	(0.7)	0	(0.0)
Haemorrhoids thrombosed	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hiatus hernia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Hyperchlorhydria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Hypoaesthesia oral	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Ileus	1	(0.3)	1	(0.3)	5	(0.7)	3	(0.4)	0	(0.0)	0	(0.0)	6	(0.4)	4	(0.2)
Impaired gastric emptying	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Inguinal hernia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

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	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Intestinal obstruction	2	(0.5)	1	(0.3)	2	(0.3)	2	(0.3)	3	(0.7)	3	(0.7)	7	(0.4)	6	(0.4)
Intestinal perforation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	2	(0.4)	2	(0.1)	2	(0.1)
Intussusception	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.4)	1	(0.2)	4	(0.2)	2	(0.1)
Irritable bowel syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Large intestinal obstruction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Large intestinal ulcer	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Large intestine polyp	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Leukoplakia oral	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lip dry	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	3	(0.2)	0	(0.0)
Lip oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Lip pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Lip swelling	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lip ulceration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Loose tooth	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Lower gastrointestinal haemorrhage	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

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	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Malabsorption	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Melaena	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	1	(0.2)	3	(0.2)	1	(0.1)
Mouth haemorrhage	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Mouth ulceration	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	5	(1.1)	0	(0.0)	8	(0.5)	0	(0.0)
Mucous stools	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Nausea	93	(24.3)	6	(1.6)	195	(25.4)	8	(1.0)	123	(26.9)	6	(1.3)	411	(25.5)	20	(1.2)
Noninfective gingivitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Odynophagia	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Oesophageal pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Oesophageal ulcer	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oesophagitis	1	(0.3)	1	(0.3)	2	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.2)
Oral disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oral mucosal blistering	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oral mucosal discolouration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oral mucosal erythema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oral pain	2	(0.5)	0	(0.0)	3	(0.4)	1	(0.1)	3	(0.7)	0	(0.0)	8	(0.5)	1	(0.1)
Painful defaecation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pancreatitis	1	(0.3)	0	(0.0)	3	(0.4)	2	(0.3)	0	(0.0)	0	(0.0)	4	(0.2)	2	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Paraesthesia oral	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peptic ulcer	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Periodontal disease	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Post-tussive vomiting	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Proctalgia	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Proctitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rectal haemorrhage	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	5	(1.1)	0	(0.0)	9	(0.6)	0	(0.0)
Rectal tenesmus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Reflux gastritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Regurgitation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Retching	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Retroperitoneal haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Saliva altered	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Salivary gland disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sensitivity of teeth	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Small intestinal obstruction	1	(0.3)	1	(0.3)	2	(0.3)	1	(0.1)	2	(0.4)	2	(0.4)	5	(0.3)	4	(0.2)
Small intestinal perforation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**243**	**(63.6)**	**33**	**(8.6)**	**475**	**(61.8)**	**58**	**(7.5)**	**302**	**(65.9)**	**42**	**(9.2)**	**1,020**	**(63.4)**	**133**	**(8.3)**
Splenic artery aneurysm	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Stomatitis	5	(1.3)	0	(0.0)	7	(0.9)	0	(0.0)	5	(1.1)	0	(0.0)	17	(1.1)	0	(0.0)
Stomatitis necrotising	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Subileus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tongue coated	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Tongue discolouration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Tongue haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tongue ulceration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tooth demineralisation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tooth disorder	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Tooth loss	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Toothache	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	4	(0.9)	0	(0.0)	10	(0.6)	0	(0.0)
Umbilical hernia, obstructive	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Upper gastrointestinal haemorrhage	1	(0.3)	1	(0.3)	2	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.2)
Vomiting	47	(12.3)	7	(1.8)	98	(12.7)	8	(1.0)	67	(14.6)	4	(0.9)	212	(13.2)	19	(1.2)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**239**	**(62.6)**	**33**	**(8.6)**	**509**	**(66.2)**	**34**	**(4.4)**	**325**	**(71.0)**	**32**	**(7.0)**	**1,073**	**(66.7)**	**99**	**(6.2)**
Adverse drug reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Asthenia	33	(8.6)	6	(1.6)	110	(14.3)	6	(0.8)	71	(15.5)	4	(0.9)	214	(13.3)	16	(1.0)
Axillary pain	6	(1.6)	0	(0.0)	16	(2.1)	1	(0.1)	6	(1.3)	0	(0.0)	28	(1.7)	1	(0.1)
Catheter site pain	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Catheter site rash	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Chest discomfort	6	(1.6)	0	(0.0)	9	(1.2)	0	(0.0)	5	(1.1)	0	(0.0)	20	(1.2)	0	(0.0)
Chest pain	17	(4.5)	2	(0.5)	27	(3.5)	0	(0.0)	23	(5.0)	2	(0.4)	67	(4.2)	4	(0.2)
Chills	24	(6.3)	0	(0.0)	49	(6.4)	0	(0.0)	31	(6.8)	0	(0.0)	104	(6.5)	0	(0.0)
Crepitations	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Cyst	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Death	4	(1.0)	4	(1.0)	3	(0.4)	3	(0.4)	2	(0.4)	2	(0.4)	9	(0.6)	9	(0.6)
Device breakage	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Device dislocation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Device failure	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Device occlusion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Early satiety	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Exercise tolerance decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Face oedema	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**239**	**(62.6)**	**33**	**(8.6)**	**509**	**(66.2)**	**34**	**(4.4)**	**325**	**(71.0)**	**32**	**(7.0)**	**1,073**	**(66.7)**	**99**	**(6.2)**
Facial pain	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Fatigue	140	(36.6)	13	(3.4)	304	(39.5)	8	(1.0)	183	(40.0)	10	(2.2)	627	(39.0)	31	(1.9)
Feeling abnormal	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Feeling cold	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Feeling drunk	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Feeling hot	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Feeling jittery	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gait disturbance	3	(0.8)	0	(0.0)	9	(1.2)	0	(0.0)	4	(0.9)	0	(0.0)	16	(1.0)	0	(0.0)
General physical health deterioration	3	(0.8)	2	(0.5)	7	(0.9)	7	(0.9)	3	(0.7)	2	(0.4)	13	(0.8)	11	(0.7)
Generalised oedema	7	(1.8)	5	(1.3)	2	(0.3)	0	(0.0)	4	(0.9)	2	(0.4)	13	(0.8)	7	(0.4)
Granuloma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hernia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hunger	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperthermia	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Hypothermia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Impaired healing	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Implant site pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Inflammation	3	(0.8)	0	(0.0)	2	(0.3)	0	(0.0)	4	(0.9)	1	(0.2)	9	(0.6)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**239**	**(62.6)**	**33**	**(8.6)**	**509**	**(66.2)**	**34**	**(4.4)**	**325**	**(71.0)**	**32**	**(7.0)**	**1,073**	**(66.7)**	**99**	**(6.2)**
Inflammatory pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Influenza like illness	15	(3.9)	0	(0.0)	37	(4.8)	0	(0.0)	22	(4.8)	1	(0.2)	74	(4.6)	1	(0.1)
Infusion site bruising	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Infusion site extravasation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	4	(0.2)	0	(0.0)
Infusion site pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Injection site extravasation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Injection site irritation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Injection site pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Injection site reaction	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Local swelling	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Localised oedema	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Malaise	15	(3.9)	1	(0.3)	7	(0.9)	0	(0.0)	4	(0.9)	2	(0.4)	26	(1.6)	3	(0.2)
Mass	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Medical device complication	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**239**	**(62.6)**	**33**	**(8.6)**	**509**	**(66.2)**	**34**	**(4.4)**	**325**	**(71.0)**	**32**	**(7.0)**	**1,073**	**(66.7)**	**99**	**(6.2)**
Medical device pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Mucosal discolouration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Mucosal dryness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Mucosal inflammation	5	(1.3)	0	(0.0)	8	(1.0)	1	(0.1)	6	(1.3)	0	(0.0)	19	(1.2)	1	(0.1)
Nodule	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Non-cardiac chest pain	1	(0.3)	1	(0.3)	8	(1.0)	0	(0.0)	4	(0.9)	0	(0.0)	13	(0.8)	1	(0.1)
Oedema	7	(1.8)	1	(0.3)	11	(1.4)	0	(0.0)	7	(1.5)	1	(0.2)	25	(1.6)	2	(0.1)
Oedema peripheral	40	(10.5)	1	(0.3)	67	(8.7)	3	(0.4)	49	(10.7)	3	(0.7)	156	(9.7)	7	(0.4)
Pain	14	(3.7)	2	(0.5)	29	(3.8)	4	(0.5)	12	(2.6)	3	(0.7)	55	(3.4)	9	(0.6)
Performance status decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral swelling	6	(1.6)	0	(0.0)	10	(1.3)	0	(0.0)	10	(2.2)	0	(0.0)	26	(1.6)	0	(0.0)
Puncture site erythema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pyrexia	44	(11.5)	1	(0.3)	92	(12.0)	2	(0.3)	68	(14.8)	1	(0.2)	204	(12.7)	4	(0.2)
Secretion discharge	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**239**	**(62.6)**	**33**	**(8.6)**	**509**	**(66.2)**	**34**	**(4.4)**	**325**	**(71.0)**	**32**	**(7.0)**	**1,073**	**(66.7)**	**99**	**(6.2)**
Sensation of foreign body	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Swelling	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Systemic inflammatory response syndrome	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	1	(0.2)	4	(0.2)	1	(0.1)
Temperature intolerance	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Thirst	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Vessel puncture site pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Xerosis	3	(0.8)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Hepatobiliary disorders	**16**	**(4.2)**	**9**	**(2.4)**	**28**	**(3.6)**	**14**	**(1.8)**	**13**	**(2.8)**	**9**	**(2.0)**	**57**	**(3.5)**	**32**	**(2.0)**
Autoimmune hepatitis	4	(1.0)	3	(0.8)	3	(0.4)	2	(0.3)	2	(0.4)	2	(0.4)	9	(0.6)	7	(0.4)
Bile duct obstruction	3	(0.8)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	2	(0.1)
Bile duct stone	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	1	(0.2)	2	(0.1)	2	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Hepatobiliary disorders	**16**	**(4.2)**	**9**	**(2.4)**	**28**	**(3.6)**	**14**	**(1.8)**	**13**	**(2.8)**	**9**	**(2.0)**	**57**	**(3.5)**	**32**	**(2.0)**
Cholangitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cholecystitis	2	(0.5)	2	(0.5)	3	(0.4)	2	(0.3)	1	(0.2)	1	(0.2)	6	(0.4)	5	(0.3)
Cholecystitis acute	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Cholestasis	1	(0.3)	0	(0.0)	6	(0.8)	1	(0.1)	1	(0.2)	1	(0.2)	8	(0.5)	2	(0.1)
Drug-induced liver injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Hepatic failure	1	(0.3)	1	(0.3)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Hepatic function abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Hepatic pain	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Hepatitis	1	(0.3)	0	(0.0)	4	(0.5)	4	(0.5)	1	(0.2)	1	(0.2)	6	(0.4)	5	(0.3)
Hepatocellular injury	0	(0.0)	0	(0.0)	3	(0.4)	1	(0.1)	0	(0.0)	0	(0.0)	3	(0.2)	1	(0.1)
Hepatomegaly	2	(0.5)	1	(0.3)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	1	(0.1)
Hepatorenal syndrome	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperbilirubinaemia	1	(0.3)	0	(0.0)	3	(0.4)	1	(0.1)	3	(0.7)	2	(0.4)	7	(0.4)	3	(0.2)
Jaundice	2	(0.5)	1	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	1	(0.1)
Immune system disorders	**12**	**(3.1)**	**0**	**(0.0)**	**21**	**(2.7)**	**2**	**(0.3)**	**11**	**(2.4)**	**1**	**(0.2)**	**44**	**(2.7)**	**3**	**(0.2)**
Allergy to animal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Immune system disorders	**12**	**(3.1)**	**0**	**(0.0)**	**21**	**(2.7)**	**2**	**(0.3)**	**11**	**(2.4)**	**1**	**(0.2)**	**44**	**(2.7)**	**3**	**(0.2)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Atopy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Autoimmune disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Contrast media allergy	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Cytokine release syndrome	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Drug hypersensitivity	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	1	(0.2)	7	(0.4)	1	(0.1)
Food allergy	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hypersensitivity	2	(0.5)	0	(0.0)	7	(0.9)	0	(0.0)	3	(0.7)	0	(0.0)	12	(0.7)	0	(0.0)
Sarcoidosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Seasonal allergy	5	(1.3)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	10	(0.6)	0	(0.0)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Abdominal wall abscess	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Abscess	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Acute tonsillitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Appendicitis perforated	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Bacteraemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bacterial sepsis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Bacterial vaginosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Body tinea	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Bronchitis	7	(1.8)	2	(0.5)	17	(2.2)	2	(0.3)	11	(2.4)	1	(0.2)	35	(2.2)	5	(0.3)
Candida infection	2	(0.5)	0	(0.0)	6	(0.8)	1	(0.1)	3	(0.7)	0	(0.0)	11	(0.7)	1	(0.1)
Catheter site infection	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Cellulitis	8	(2.1)	3	(0.8)	14	(1.8)	8	(1.0)	7	(1.5)	3	(0.7)	29	(1.8)	14	(0.9)
Chronic sinusitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Clostridium difficile colitis	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Clostridium difficile infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	1	(0.2)	2	(0.1)	2	(0.1)
Conjunctivitis	3	(0.8)	0	(0.0)	13	(1.7)	0	(0.0)	8	(1.7)	0	(0.0)	24	(1.5)	0	(0.0)
Cystitis	5	(1.3)	0	(0.0)	6	(0.8)	0	(0.0)	3	(0.7)	0	(0.0)	14	(0.9)	0	(0.0)
Cytomegalovirus colitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatophytosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Device related infection	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Diverticulitis	1	(0.3)	1	(0.3)	3	(0.4)	1	(0.1)	1	(0.2)	0	(0.0)	5	(0.3)	2	(0.1)
Ear infection	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Ear infection fungal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Encephalitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Enterocolitis infectious	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Erysipelas	5	(1.3)	1	(0.3)	6	(0.8)	3	(0.4)	2	(0.4)	0	(0.0)	13	(0.8)	4	(0.2)
Erythema migrans	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erythrasma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Escherichia bacteraemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Escherichia urinary tract infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Eye infection	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Febrile infection	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Folliculitis	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Fungal infection	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Fungal oesophagitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Fungal skin infection	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Furuncle	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Gastroenteritis	4	(1.0)	0	(0.0)	2	(0.3)	0	(0.0)	7	(1.5)	1	(0.2)	13	(0.8)	1	(0.1)
Gastroenteritis viral	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Gastrointestinal viral infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Genital herpes	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Genital infection fungal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Gingivitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Helicobacter infection	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Herpes simplex	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Herpes virus infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	4	(0.2)	0	(0.0)
Herpes zoster	1	(0.3)	0	(0.0)	4	(0.5)	1	(0.1)	6	(1.3)	0	(0.0)	11	(0.7)	1	(0.1)
Hordeolum	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Incision site abscess	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Infected dermal cyst	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Infection	3	(0.8)	1	(0.3)	5	(0.7)	1	(0.1)	0	(0.0)	0	(0.0)	8	(0.5)	2	(0.1)
Infectious pleural effusion	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)
Influenza	10	(2.6)	0	(0.0)	20	(2.6)	1	(0.1)	4	(0.9)	0	(0.0)	34	(2.1)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Intervertebral discitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Kidney infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Klebsiella infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Laryngitis	0	(0.0)	0	(0.0)	6	(0.8)	0	(0.0)	1	(0.2)	0	(0.0)	7	(0.4)	0	(0.0)
Lobar pneumonia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Localised infection	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	4	(0.2)	1	(0.1)
Lower respiratory tract infection	1	(0.3)	0	(0.0)	6	(0.8)	0	(0.0)	5	(1.1)	0	(0.0)	12	(0.7)	0	(0.0)
Lung infection	6	(1.6)	1	(0.3)	6	(0.8)	1	(0.1)	3	(0.7)	0	(0.0)	15	(0.9)	2	(0.1)
Lyme disease	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Lymph gland infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphangitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Mastitis	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Nail bed infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nasopharyngitis	37	(9.7)	0	(0.0)	53	(6.9)	0	(0.0)	43	(9.4)	0	(0.0)	133	(8.3)	0	(0.0)
Oesophageal candidiasis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Onychomycosis	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Ophthalmic herpes zoster	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oral candidiasis	3	(0.8)	0	(0.0)	14	(1.8)	0	(0.0)	2	(0.4)	0	(0.0)	19	(1.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Oral fungal infection	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Oral herpes	3	(0.8)	0	(0.0)	4	(0.5)	0	(0.0)	7	(1.5)	0	(0.0)	14	(0.9)	0	(0.0)
Oral infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Otitis externa	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Otitis media	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Paronychia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Pelvic abscess	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Penile abscess	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Penile infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pharyngitis	3	(0.8)	1	(0.3)	6	(0.8)	0	(0.0)	4	(0.9)	0	(0.0)	13	(0.8)	1	(0.1)
Pneumonia	11	(2.9)	5	(1.3)	14	(1.8)	6	(0.8)	13	(2.8)	9	(2.0)	38	(2.4)	20	(1.2)
Pneumonia klebsiella	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Post procedural cellulitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Post procedural infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Postoperative wound infection	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Pseudomonas infection	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pulpitis dental	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Pyelonephritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rash pustular	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Respiratory tract infection	2	(0.5)	0	(0.0)	4	(0.5)	1	(0.1)	1	(0.2)	0	(0.0)	7	(0.4)	1	(0.1)
Respiratory tract infection viral	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Rhinitis	9	(2.4)	0	(0.0)	11	(1.4)	0	(0.0)	5	(1.1)	0	(0.0)	25	(1.6)	0	(0.0)
Salmonellosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sepsis	3	(0.8)	3	(0.8)	3	(0.4)	3	(0.4)	5	(1.1)	4	(0.9)	11	(0.7)	10	(0.6)
Septic shock	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Sinusitis	10	(2.6)	0	(0.0)	15	(2.0)	1	(0.1)	17	(3.7)	0	(0.0)	42	(2.6)	1	(0.1)
Sinusitis bacterial	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin candida	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin infection	8	(2.1)	2	(0.5)	6	(0.8)	1	(0.1)	9	(2.0)	1	(0.2)	23	(1.4)	4	(0.2)
Soft tissue infection	2	(0.5)	1	(0.3)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	3	(0.2)	2	(0.1)
Staphylococcal infection	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Staphylococcal skin infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Subcutaneous abscess	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Tinea cruris	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tinea infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Tinea pedis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Tinea versicolour	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Tooth abscess	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Tooth infection	4	(1.0)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	9	(0.6)	0	(0.0)
Tracheitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	3	(0.2)	0	(0.0)
Tuberculosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Upper respiratory tract infection	24	(6.3)	1	(0.3)	40	(5.2)	0	(0.0)	38	(8.3)	1	(0.2)	102	(6.3)	2	(0.1)
Urinary tract infection	24	(6.3)	2	(0.5)	44	(5.7)	4	(0.5)	30	(6.6)	4	(0.9)	98	(6.1)	10	(0.6)
Urinary tract infection viral	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vaginal infection	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Vestibular neuronitis	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Viral infection	2	(0.5)	2	(0.5)	5	(0.7)	1	(0.1)	4	(0.9)	0	(0.0)	11	(0.7)	3	(0.2)
Viral pharyngitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Viral rhinitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Viral sinusitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Viral upper respiratory tract infection	1	(0.3)	0	(0.0)	5	(0.7)	1	(0.1)	0	(0.0)	0	(0.0)	6	(0.4)	1	(0.1)
Vulvitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**168**	**(44.0)**	**29**	**(7.6)**	**291**	**(37.8)**	**41**	**(5.3)**	**203**	**(44.3)**	**24**	**(5.2)**	**662**	**(41.1)**	**94**	**(5.8)**
Vulvovaginal candidiasis	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Vulvovaginal mycotic infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Wound infection	5	(1.3)	2	(0.5)	3	(0.4)	0	(0.0)	5	(1.1)	0	(0.0)	13	(0.8)	2	(0.1)
Yersinia infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Injury, poisoning and procedural complications	**62**	**(16.2)**	**4**	**(1.0)**	**93**	**(12.1)**	**11**	**(1.4)**	**57**	**(12.4)**	**3**	**(0.7)**	**212**	**(13.2)**	**18**	**(1.1)**
Accidental overdose	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Arthropod bite	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Arthropod sting	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Back injury	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Brain herniation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Burns second degree	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Chillblains	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Clavicle fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Concussion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Contrast media reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

C Confidential

付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**62**	**(16.2)**	**4**	**(1.0)**	**93**	**(12.1)**	**11**	**(1.4)**	**57**	**(12.4)**	**3**	**(0.7)**	**212**	**(13.2)**	**18**	**(1.1)**
Contusion	4	(1.0)	0	(0.0)	8	(1.0)	0	(0.0)	8	(1.7)	0	(0.0)	20	(1.2)	0	(0.0)
Corneal abrasion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ear abrasion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eschar	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Excoriation	4	(1.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Face injury	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Facial bones fracture	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Fall	9	(2.4)	1	(0.3)	12	(1.6)	0	(0.0)	11	(2.4)	0	(0.0)	32	(2.0)	1	(0.1)
Foot fracture	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Fracture	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hand fracture	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hip fracture	0	(0.0)	0	(0.0)	2	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Humerus fracture	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Incision site complication	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Incision site haemorrhage	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Incision site pain	0	(0.0)	0	(0.0)	6	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.4)	0	(0.0)
Incision site pruritus	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Incision site ulcer	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**62**	**(16.2)**	**4**	**(1.0)**	**93**	**(12.1)**	**11**	**(1.4)**	**57**	**(12.4)**	**3**	**(0.7)**	**212**	**(13.2)**	**18**	**(1.1)**
Infusion related reaction	1	(0.3)	0	(0.0)	9	(1.2)	0	(0.0)	4	(0.9)	0	(0.0)	14	(0.9)	0	(0.0)
Joint dislocation	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Joint injury	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	1	(0.2)	2	(0.1)	1	(0.1)
Laceration	5	(1.3)	0	(0.0)	4	(0.5)	0	(0.0)	5	(1.1)	0	(0.0)	14	(0.9)	0	(0.0)
Ligament sprain	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Limb injury	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Lip injury	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Lower limb fracture	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Meniscus injury	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle contusion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle strain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Periorbital contusion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Post procedural complication	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Post procedural discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Post procedural haematoma	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Post procedural haemorrhage	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**62**	**(16.2)**	**4**	**(1.0)**	**93**	**(12.1)**	**11**	**(1.4)**	**57**	**(12.4)**	**3**	**(0.7)**	**212**	**(13.2)**	**18**	**(1.1)**
Post procedural hypothyroidism	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Post-traumatic pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Procedural pain	4	(1.0)	0	(0.0)	7	(0.9)	1	(0.1)	5	(1.1)	0	(0.0)	16	(1.0)	1	(0.1)
Radiation injury	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Radiation necrosis	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	1	(0.2)	1	(0.2)	3	(0.2)	2	(0.1)
Radiation proctitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Radiation skin injury	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	7	(0.4)	0	(0.0)
Rib fracture	1	(0.3)	1	(0.3)	7	(0.9)	2	(0.3)	2	(0.4)	0	(0.0)	10	(0.6)	3	(0.2)
Scratch	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Seroma	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skeletal injury	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Skin abrasion	4	(1.0)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Skin wound	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Spinal compression fracture	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Spinal fracture	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Sternal fracture	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Stress fracture	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Subdural haematoma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**62**	**(16.2)**	**4**	**(1.0)**	**93**	**(12.1)**	**11**	**(1.4)**	**57**	**(12.4)**	**3**	**(0.7)**	**212**	**(13.2)**	**18**	**(1.1)**
Sunburn	3	(0.8)	0	(0.0)	2	(0.3)	0	(0.0)	6	(1.3)	0	(0.0)	11	(0.7)	0	(0.0)
Synovial rupture	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tendon rupture	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thermal burn	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Tooth fracture	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Transfusion reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Urinary retention postoperative	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Wound	3	(0.8)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	9	(0.6)	0	(0.0)
Wound complication	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Wound decomposition	1	(0.3)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	3	(0.2)	1	(0.1)
Wound haemorrhage	1	(0.3)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	3	(0.2)	1	(0.1)
Wound necrosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Wound secretion	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Wrist fracture	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Activated partial thromboplastin time prolonged	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Alanine aminotransferase	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Alanine aminotransferase decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Alanine aminotransferase increased	20	(5.2)	1	(0.3)	40	(5.2)	8	(1.0)	31	(6.8)	2	(0.4)	91	(5.7)	11	(0.7)
Amylase increased	3	(0.8)	1	(0.3)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	5	(0.3)	2	(0.1)
Aortic bruit	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aspartate aminotransferase increased	20	(5.2)	2	(0.5)	43	(5.6)	9	(1.2)	33	(7.2)	2	(0.4)	96	(6.0)	13	(0.8)
Autoantibody positive	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bilirubin conjugated increased	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.4)	0	(0.0)	4	(0.2)	1	(0.1)
Biopsy skin	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood albumin decreased	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Blood albumin increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood alkaline phosphatase	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood alkaline phosphatase decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood alkaline phosphatase increased	14	(3.7)	2	(0.5)	30	(3.9)	3	(0.4)	13	(2.8)	2	(0.4)	57	(3.5)	7	(0.4)
Blood bicarbonate decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood bicarbonate increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Blood bilirubin	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood bilirubin increased	9	(2.4)	4	(1.0)	9	(1.2)	3	(0.4)	14	(3.1)	1	(0.2)	32	(2.0)	8	(0.5)
Blood calcium decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Blood calcium increased	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Blood cholesterol increased	5	(1.3)	0	(0.0)	12	(1.6)	1	(0.1)	7	(1.5)	0	(0.0)	24	(1.5)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Blood corticotrophin decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Blood corticotrophin increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood cortisol decreased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Blood creatine phosphokinase increased	3	(0.8)	1	(0.3)	2	(0.3)	2	(0.3)	1	(0.2)	0	(0.0)	6	(0.4)	3	(0.2)
Blood creatinine increased	11	(2.9)	0	(0.0)	23	(3.0)	1	(0.1)	20	(4.4)	0	(0.0)	54	(3.4)	1	(0.1)
Blood folate decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood glucose abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood glucose increased	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	1	(0.2)	0	(0.0)	3	(0.2)	1	(0.1)
Blood immunoglobulin G decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood iron decreased	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Blood lactate dehydrogenase increased	0	(0.0)	0	(0.0)	8	(1.0)	1	(0.1)	11	(2.4)	2	(0.4)	19	(1.2)	3	(0.2)
Blood lactic acid increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood luteinising hormone decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood magnesium decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood magnesium increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood parathyroid hormone increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood phosphorus decreased	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Blood phosphorus increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood potassium decreased	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Blood potassium increased	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Blood pressure diastolic increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood sodium decreased	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Blood testosterone decreased	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	4	(0.9)	0	(0.0)	7	(0.4)	0	(0.0)
Blood testosterone increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood thyroid stimulating hormone decreased	3	(0.8)	0	(0.0)	11	(1.4)	0	(0.0)	4	(0.9)	0	(0.0)	18	(1.1)	0	(0.0)
Blood thyroid stimulating hormone increased	4	(1.0)	0	(0.0)	10	(1.3)	0	(0.0)	2	(0.4)	0	(0.0)	16	(1.0)	0	(0.0)
Blood triglycerides increased	5	(1.3)	1	(0.3)	12	(1.6)	0	(0.0)	4	(0.9)	0	(0.0)	21	(1.3)	1	(0.1)
Blood urea increased	4	(1.0)	0	(0.0)	4	(0.5)	0	(0.0)	3	(0.7)	0	(0.0)	11	(0.7)	0	(0.0)
Blood uric acid increased	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	2	(0.4)	0	(0.0)	10	(0.6)	0	(0.0)
Blood urine	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Blood urine present	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Body temperature increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Brain natriuretic peptide increased	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Breath sounds abnormal	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Cardiac murmur	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cardiac murmur functional	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Computerised tomogram thorax abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cortisol free urine decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Creatinine renal clearance increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Electrocardiogram QT prolonged	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Electrocardiogram ST segment abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Electrocardiogram T wave inversion	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Electrocardiogram abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Electrocardiogram change	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Electrocardiogram low voltage	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Electrocardiogram repolarisation abnormality	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eosinophil count increased	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Fibrin D dimer increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Gamma-glutamyltransferase decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gamma-glutamyltransferase increased	6	(1.6)	2	(0.5)	6	(0.8)	3	(0.4)	13	(2.8)	2	(0.4)	25	(1.6)	7	(0.4)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Glucose urine	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Haematocrit decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haemoglobin decreased	4	(1.0)	0	(0.0)	3	(0.4)	1	(0.1)	2	(0.4)	0	(0.0)	9	(0.6)	1	(0.1)
Haemoglobin increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haemoglobin urine	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Heart rate increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Heart rate irregular	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hepatic enzyme increased	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	1	(0.2)	3	(0.2)	1	(0.1)
International normalised ratio increased	2	(0.5)	1	(0.3)	3	(0.4)	2	(0.3)	4	(0.9)	0	(0.0)	9	(0.6)	3	(0.2)
Intraocular pressure test abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Lipase	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lipase increased	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	1	(0.2)	1	(0.2)	3	(0.2)	2	(0.1)
Liver function test abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Lymphocyte count decreased	8	(2.1)	3	(0.8)	13	(1.7)	6	(0.8)	7	(1.5)	1	(0.2)	28	(1.7)	10	(0.6)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Medical observation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neutrophil count decreased	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Neutrophil count increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Nitrite urine present	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nuclear magnetic resonance imaging brain abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Occult blood	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Oxygen saturation decreased	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Pancreatic enzymes decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pancreatic enzymes increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Platelet count decreased	4	(1.0)	0	(0.0)	11	(1.4)	1	(0.1)	7	(1.5)	1	(0.2)	22	(1.4)	2	(0.1)
Platelet count increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Thyroglobulin increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Thyroid function test abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroxine decreased	1	(0.3)	0	(0.0)	6	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Thyroxine free increased	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Thyroxine increased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Transaminases increased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Tri-iodothyronine decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	4	(0.2)	0	(0.0)
Tri-iodothyronine free decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tri-iodothyronine increased	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Troponin increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Urine leukocyte esterase positive	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Urine output decreased	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Vitamin D decreased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Weight decreased	26	(6.8)	2	(0.5)	59	(7.7)	2	(0.3)	25	(5.5)	0	(0.0)	110	(6.8)	4	(0.2)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**128**	**(33.5)**	**21**	**(5.5)**	**222**	**(28.9)**	**33**	**(4.3)**	**138**	**(30.1)**	**12**	**(2.6)**	**488**	**(30.3)**	**66**	**(4.1)**
Weight increased	13	(3.4)	1	(0.3)	20	(2.6)	0	(0.0)	11	(2.4)	0	(0.0)	44	(2.7)	1	(0.1)
White blood cell count decreased	6	(1.6)	1	(0.3)	9	(1.2)	0	(0.0)	2	(0.4)	0	(0.0)	17	(1.1)	1	(0.1)
White blood cell count increased	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Metabolism and nutrition disorders	**138**	**(36.1)**	**38**	**(9.9)**	**268**	**(34.9)**	**45**	**(5.9)**	**172**	**(37.6)**	**41**	**(9.0)**	**578**	**(35.9)**	**124**	**(7.7)**
Acidosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Alcohol intolerance	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cachexia	2	(0.5)	2	(0.5)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.2)
Cell death	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	1	(0.2)	2	(0.1)	1	(0.1)
Cow's milk intolerance	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Decreased appetite	68	(17.8)	1	(0.3)	149	(19.4)	7	(0.9)	86	(18.8)	3	(0.7)	303	(18.8)	11	(0.7)
Dehydration	22	(5.8)	10	(2.6)	23	(3.0)	3	(0.4)	17	(3.7)	3	(0.7)	62	(3.9)	16	(1.0)
Diabetes mellitus	4	(1.0)	3	(0.8)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	7	(0.4)	3	(0.2)
Diabetes mellitus inadequate control	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Diabetic ketoacidosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**138**	**(36.1)**	**38**	**(9.9)**	**268**	**(34.9)**	**45**	**(5.9)**	**172**	**(37.6)**	**41**	**(9.0)**	**578**	**(35.9)**	**124**	**(7.7)**
Electrolyte imbalance	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	1	(0.2)	0	(0.0)	3	(0.2)	1	(0.1)
Failure to thrive	1	(0.3)	1	(0.3)	2	(0.3)	2	(0.3)	2	(0.4)	2	(0.4)	5	(0.3)	5	(0.3)
Fluid overload	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Fluid retention	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Glucose tolerance impaired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Gout	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	4	(0.9)	1	(0.2)	12	(0.7)	1	(0.1)
Hyperalbuminaemia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypercalcaemia	7	(1.8)	1	(0.3)	9	(1.2)	1	(0.1)	10	(2.2)	0	(0.0)	26	(1.6)	2	(0.1)
Hypercholesterolaemia	4	(1.0)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	10	(0.6)	0	(0.0)
Hyperglycaemia	14	(3.7)	4	(1.0)	28	(3.6)	5	(0.7)	18	(3.9)	5	(1.1)	60	(3.7)	14	(0.9)
Hyperkalaemia	10	(2.6)	2	(0.5)	16	(2.1)	0	(0.0)	10	(2.2)	1	(0.2)	36	(2.2)	3	(0.2)
Hyperlipidaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Hypermagnesaemia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Hypernatraemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperphosphataemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Hypertriglyceridaemia	9	(2.4)	2	(0.5)	25	(3.3)	5	(0.7)	15	(3.3)	2	(0.4)	49	(3.0)	9	(0.6)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**138**	**(36.1)**	**38**	**(9.9)**	**268**	**(34.9)**	**45**	**(5.9)**	**172**	**(37.6)**	**41**	**(9.0)**	**578**	**(35.9)**	**124**	**(7.7)**
Hyperuricaemia	9	(2.4)	3	(0.8)	14	(1.8)	2	(0.3)	4	(0.9)	0	(0.0)	27	(1.7)	5	(0.3)
Hypoalbuminaemia	7	(1.8)	2	(0.5)	23	(3.0)	3	(0.4)	18	(3.9)	4	(0.9)	48	(3.0)	9	(0.6)
Hypocalcaemia	3	(0.8)	1	(0.3)	17	(2.2)	0	(0.0)	8	(1.7)	0	(0.0)	28	(1.7)	1	(0.1)
Hypoglycaemia	2	(0.5)	0	(0.0)	4	(0.5)	2	(0.3)	2	(0.4)	1	(0.2)	8	(0.5)	3	(0.2)
Hypokalaemia	10	(2.6)	2	(0.5)	31	(4.0)	4	(0.5)	27	(5.9)	7	(1.5)	68	(4.2)	13	(0.8)
Hypomagnesaemia	4	(1.0)	0	(0.0)	18	(2.3)	0	(0.0)	9	(2.0)	0	(0.0)	31	(1.9)	0	(0.0)
Hyponatraemia	28	(7.3)	11	(2.9)	32	(4.2)	14	(1.8)	26	(5.7)	13	(2.8)	86	(5.3)	38	(2.4)
Hypophagia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hypophosphataemia	8	(2.1)	1	(0.3)	12	(1.6)	2	(0.3)	8	(1.7)	4	(0.9)	28	(1.7)	7	(0.4)
Hypovolaemia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Increased appetite	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Insulin resistant diabetes	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Iron deficiency	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Lactic acidosis	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Malnutrition	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	1	(0.2)	4	(0.2)	1	(0.1)
Marasmus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Metabolic acidosis	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	1	(0.1)
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Tumour lysis syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**138**	**(36.1)**	**38**	**(9.9)**	**268**	**(34.9)**	**45**	**(5.9)**	**172**	**(37.6)**	**41**	**(9.0)**	**578**	**(35.9)**	**124**	**(7.7)**
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Vitamin B12 deficiency	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Vitamin D deficiency	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Musculoskeletal and connective tissue disorders	**187**	**(49.0)**	**12**	**(3.1)**	**387**	**(50.3)**	**28**	**(3.6)**	**262**	**(57.2)**	**18**	**(3.9)**	**836**	**(52.0)**	**58**	**(3.6)**
Amyotrophy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ankylosing spondylitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Arthralgia	68	(17.8)	1	(0.3)	148	(19.2)	4	(0.5)	98	(21.4)	1	(0.2)	314	(19.5)	6	(0.4)
Arthritis	7	(1.8)	0	(0.0)	6	(0.8)	0	(0.0)	13	(2.8)	0	(0.0)	26	(1.6)	0	(0.0)
Arthropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Axillary mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Back disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Back pain	45	(11.8)	2	(0.5)	83	(10.8)	8	(1.0)	61	(13.3)	3	(0.7)	189	(11.7)	13	(0.8)
Bone pain	3	(0.8)	0	(0.0)	12	(1.6)	0	(0.0)	9	(2.0)	0	(0.0)	24	(1.5)	0	(0.0)
Bursa disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bursitis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**187**	**(49.0)**	**12**	**(3.1)**	**387**	**(50.3)**	**28**	**(3.6)**	**262**	**(57.2)**	**18**	**(3.9)**	**836**	**(52.0)**	**58**	**(3.6)**
Chondrocalcinosis pyrophosphate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Coccydynia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Costochondritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Exostosis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Fibromyalgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Fistula	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Flank pain	8	(2.1)	1	(0.3)	18	(2.3)	1	(0.1)	8	(1.7)	0	(0.0)	34	(2.1)	2	(0.1)
Fracture pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Groin pain	3	(0.8)	0	(0.0)	10	(1.3)	2	(0.3)	8	(1.7)	0	(0.0)	21	(1.3)	2	(0.1)
Growing pains	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Inguinal mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Intervertebral disc protrusion	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Joint effusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Joint instability	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Joint range of motion decreased	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	4	(0.9)	1	(0.2)	6	(0.4)	1	(0.1)
Joint stiffness	5	(1.3)	0	(0.0)	5	(0.7)	0	(0.0)	2	(0.4)	0	(0.0)	12	(0.7)	0	(0.0)
Joint swelling	4	(1.0)	0	(0.0)	7	(0.9)	0	(0.0)	4	(0.9)	0	(0.0)	15	(0.9)	0	(0.0)
Kyphosis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Ligamentitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**187**	**(49.0)**	**12**	**(3.1)**	**387**	**(50.3)**	**28**	**(3.6)**	**262**	**(57.2)**	**18**	**(3.9)**	**836**	**(52.0)**	**58**	**(3.6)**
Limb discomfort	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Lower extremity mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Mobility decreased	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Muscle atrophy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle fatigue	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Muscle spasms	12	(3.1)	0	(0.0)	17	(2.2)	0	(0.0)	18	(3.9)	0	(0.0)	47	(2.9)	0	(0.0)
Muscle tightness	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Muscle twitching	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Muscular weakness	17	(4.5)	3	(0.8)	27	(3.5)	2	(0.3)	13	(2.8)	2	(0.4)	57	(3.5)	7	(0.4)
Musculoskeletal chest pain	11	(2.9)	0	(0.0)	21	(2.7)	1	(0.1)	18	(3.9)	1	(0.2)	50	(3.1)	2	(0.1)
Musculoskeletal discomfort	4	(1.0)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	10	(0.6)	0	(0.0)
Musculoskeletal pain	30	(7.9)	3	(0.8)	50	(6.5)	2	(0.3)	32	(7.0)	3	(0.7)	112	(7.0)	8	(0.5)
Musculoskeletal stiffness	7	(1.8)	0	(0.0)	12	(1.6)	0	(0.0)	8	(1.7)	0	(0.0)	27	(1.7)	0	(0.0)
Myalgia	35	(9.2)	3	(0.8)	66	(8.6)	1	(0.1)	66	(14.4)	2	(0.4)	167	(10.4)	6	(0.4)
Myalgia intercostal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Myopathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Myositis	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**187**	**(49.0)**	**12**	**(3.1)**	**387**	**(50.3)**	**28**	**(3.6)**	**262**	**(57.2)**	**18**	**(3.9)**	**836**	**(52.0)**	**58**	**(3.6)**
Neck mass	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Neck pain	14	(3.7)	0	(0.0)	19	(2.5)	1	(0.1)	16	(3.5)	0	(0.0)	49	(3.0)	1	(0.1)
Nodal osteoarthritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Osteitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Osteoarthritis	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Osteolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Osteoporosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pain in extremity	39	(10.2)	2	(0.5)	61	(7.9)	3	(0.4)	46	(10.0)	2	(0.4)	146	(9.1)	7	(0.4)
Pain in jaw	5	(1.3)	0	(0.0)	9	(1.2)	0	(0.0)	2	(0.4)	0	(0.0)	16	(1.0)	0	(0.0)
Pathological fracture	0	(0.0)	0	(0.0)	3	(0.4)	2	(0.3)	3	(0.7)	1	(0.2)	6	(0.4)	3	(0.2)
Periarthritis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Plantar fasciitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Polyarthritis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Polymyalgia rheumatica	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Rheumatic disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rotator cuff syndrome	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**187**	**(49.0)**	**12**	**(3.1)**	**387**	**(50.3)**	**28**	**(3.6)**	**262**	**(57.2)**	**18**	**(3.9)**	**836**	**(52.0)**	**58**	**(3.6)**
Sjogren's syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Spinal column stenosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Spinal osteoarthritis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Spinal pain	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Spondylolisthesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Synovial cyst	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Synovitis	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Temporomandibular joint syndrome	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Tendon disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tendon pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tendonitis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Tenosynovitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Torticollis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Trigger finger	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Trismus	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Upper extremity mass	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**30**	**(7.9)**	**11**	**(2.9)**	**77**	**(10.0)**	**19**	**(2.5)**	**55**	**(12.0)**	**14**	**(3.1)**	**162**	**(10.1)**	**44**	**(2.7)**
Abdominal neoplasm	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Acrochordon	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Adenocarcinoma	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Adenocarcinoma gastric	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Basal cell carcinoma	5	(1.3)	1	(0.3)	5	(0.7)	1	(0.1)	4	(0.9)	1	(0.2)	14	(0.9)	3	(0.2)
Basosquamous carcinoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Cancer pain	3	(0.8)	2	(0.5)	7	(0.9)	1	(0.1)	1	(0.2)	1	(0.2)	11	(0.7)	4	(0.2)
Cerebral haemangioma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Desmoplastic melanoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrointestinal carcinoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Haemangioma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Infected neoplasm	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	4	(0.9)	0	(0.0)	5	(0.3)	0	(0.0)
Intracranial tumour haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.4)	2	(0.4)	3	(0.2)	3	(0.2)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**30**	**(7.9)**	**11**	**(2.9)**	**77**	**(10.0)**	**19**	**(2.5)**	**55**	**(12.0)**	**14**	**(3.1)**	**162**	**(10.1)**	**44**	**(2.7)**
Keratoacanthoma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lipoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Lymphangiosis carcinomatosa	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Malignant melanoma	1	(0.3)	0	(0.0)	2	(0.3)	1	(0.1)	2	(0.4)	1	(0.2)	5	(0.3)	2	(0.1)
Malignant melanoma in situ	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Melanocytic naevus	2	(0.5)	0	(0.0)	5	(0.7)	0	(0.0)	3	(0.7)	0	(0.0)	10	(0.6)	0	(0.0)
Metastases to bone	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Metastases to central nervous system	3	(0.8)	2	(0.5)	3	(0.4)	2	(0.3)	1	(0.2)	1	(0.2)	7	(0.4)	5	(0.3)
Metastases to lymph nodes	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Metastases to meninges	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Metastases to muscle	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**30**	**(7.9)**	**11**	**(2.9)**	**77**	**(10.0)**	**19**	**(2.5)**	**55**	**(12.0)**	**14**	**(3.1)**	**162**	**(10.1)**	**44**	**(2.7)**
Metastatic malignant melanoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	2	(0.4)	3	(0.2)	2	(0.1)
Metastatic pain	2	(0.5)	1	(0.3)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	1	(0.1)
Neoplasm skin	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Neoplasm swelling	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oncologic complication	2	(0.5)	1	(0.3)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	1	(0.1)
Papillary thyroid cancer	0	(0.0)	0	(0.0)	2	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Papilloma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Seborrhoeic keratosis	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	7	(1.5)	0	(0.0)	11	(0.7)	0	(0.0)
Skin neoplasm bleeding	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Skin papilloma	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Squamous cell carcinoma	2	(0.5)	1	(0.3)	7	(0.9)	5	(0.7)	6	(1.3)	1	(0.2)	15	(0.9)	7	(0.4)
Squamous cell carcinoma of skin	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**30**	**(7.9)**	**11**	**(2.9)**	**77**	**(10.0)**	**19**	**(2.5)**	**55**	**(12.0)**	**14**	**(3.1)**	**162**	**(10.1)**	**44**	**(2.7)**
Thyroid neoplasm	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tumour haemorrhage	2	(0.5)	0	(0.0)	5	(0.7)	1	(0.1)	2	(0.4)	0	(0.0)	9	(0.6)	1	(0.1)
Tumour necrosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Tumour pain	6	(1.6)	3	(0.8)	21	(2.7)	3	(0.4)	10	(2.2)	0	(0.0)	37	(2.3)	6	(0.4)
Vulval cancer metastatic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Nervous system disorders	**140**	**(36.6)**	**18**	**(4.7)**	**280**	**(36.4)**	**32**	**(4.2)**	**190**	**(41.5)**	**17**	**(3.7)**	**610**	**(37.9)**	**67**	**(4.2)**
Action tremor	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ageusia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Akathisia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Altered state of consciousness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Amnesia	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	4	(0.9)	0	(0.0)	9	(0.6)	0	(0.0)
Amnestic disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Anosmia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Aphasia	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	4	(0.9)	3	(0.7)	9	(0.6)	3	(0.2)
Aphonia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Ataxia	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**140**	**(36.6)**	**18**	**(4.7)**	**280**	**(36.4)**	**32**	**(4.2)**	**190**	**(41.5)**	**17**	**(3.7)**	**610**	**(37.9)**	**67**	**(4.2)**
Balance disorder	2	(0.5)	0	(0.0)	9	(1.2)	0	(0.0)	4	(0.9)	0	(0.0)	15	(0.9)	0	(0.0)
Brain oedema	0	(0.0)	0	(0.0)	3	(0.4)	3	(0.4)	2	(0.4)	1	(0.2)	5	(0.3)	4	(0.2)
Burning sensation	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Carpal tunnel syndrome	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Cerebellar syndrome	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cerebral haemorrhage	1	(0.3)	1	(0.3)	1	(0.1)	1	(0.1)	1	(0.2)	0	(0.0)	3	(0.2)	2	(0.1)
Cerebral infarction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cerebrovascular accident	2	(0.5)	1	(0.3)	2	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	4	(0.2)	3	(0.2)
Cognitive disorder	2	(0.5)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	3	(0.2)	1	(0.1)
Coordination abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Depressed level of consciousness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Developmental coordination disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Disturbance in attention	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Dizziness	33	(8.6)	1	(0.3)	59	(7.7)	4	(0.5)	44	(9.6)	0	(0.0)	136	(8.5)	5	(0.3)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**140**	**(36.6)**	**18**	**(4.7)**	**280**	**(36.4)**	**32**	**(4.2)**	**190**	**(41.5)**	**17**	**(3.7)**	**610**	**(37.9)**	**67**	**(4.2)**
Dizziness postural	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Dysaesthesia	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Dysarthria	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Dysgeusia	10	(2.6)	0	(0.0)	17	(2.2)	0	(0.0)	21	(4.6)	0	(0.0)	48	(3.0)	0	(0.0)
Dyskinesia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Encephalopathy	3	(0.8)	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	3	(0.2)
Epilepsy	1	(0.3)	1	(0.3)	1	(0.1)	1	(0.1)	2	(0.4)	2	(0.4)	4	(0.2)	4	(0.2)
Facial nerve disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Guillain-Barre syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Haemorrhage intracranial	2	(0.5)	1	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	1	(0.1)
Haemorrhagic stroke	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Head discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Headache	43	(11.3)	2	(0.5)	122	(15.9)	3	(0.4)	90	(19.7)	2	(0.4)	255	(15.8)	7	(0.4)
Hemiparesis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	1	(0.2)	4	(0.2)	1	(0.1)
Hydrocephalus	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperaesthesia	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Hypersomnia	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Hypoaesthesia	12	(3.1)	0	(0.0)	12	(1.6)	0	(0.0)	10	(2.2)	0	(0.0)	34	(2.1)	0	(0.0)
Hypogeusia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**140**	**(36.6)**	**18**	**(4.7)**	**280**	**(36.4)**	**32**	**(4.2)**	**190**	**(41.5)**	**17**	**(3.7)**	**610**	**(37.9)**	**67**	**(4.2)**
Hypotonia	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Ischaemic stroke	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Judgement impaired	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lacunar infarction	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lethargy	6	(1.6)	0	(0.0)	5	(0.7)	1	(0.1)	5	(1.1)	0	(0.0)	16	(1.0)	1	(0.1)
Loss of consciousness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Lumbar radiculopathy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Memory impairment	7	(1.8)	0	(0.0)	6	(0.8)	0	(0.0)	7	(1.5)	0	(0.0)	20	(1.2)	0	(0.0)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Migraine	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Migraine with aura	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Monoparesis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Myoclonus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Nerve root compression	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**140**	**(36.6)**	**18**	**(4.7)**	**280**	**(36.4)**	**32**	**(4.2)**	**190**	**(41.5)**	**17**	**(3.7)**	**610**	**(37.9)**	**67**	**(4.2)**
Nervous system disorder	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Neuralgia	1	(0.3)	0	(0.0)	7	(0.9)	1	(0.1)	4	(0.9)	0	(0.0)	12	(0.7)	1	(0.1)
Neuropathy peripheral	12	(3.1)	0	(0.0)	18	(2.3)	1	(0.1)	13	(2.8)	0	(0.0)	43	(2.7)	1	(0.1)
Normal pressure hydrocephalus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Optic neuritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Paraesthesia	14	(3.7)	1	(0.3)	24	(3.1)	0	(0.0)	16	(3.5)	0	(0.0)	54	(3.4)	1	(0.1)
Paralysis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Partial seizures	3	(0.8)	1	(0.3)	1	(0.1)	0	(0.0)	2	(0.4)	1	(0.2)	6	(0.4)	2	(0.1)
Peripheral motor neuropathy	2	(0.5)	1	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	1	(0.1)
Peripheral sensory neuropathy	5	(1.3)	0	(0.0)	5	(0.7)	0	(0.0)	4	(0.9)	0	(0.0)	14	(0.9)	0	(0.0)
Peroneal nerve palsy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Phantom pain	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Polyneuropathy	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Poor quality sleep	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Post herpetic neuralgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	3	(0.2)	0	(0.0)

C Confidential

付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**140**	**(36.6)**	**18**	**(4.7)**	**280**	**(36.4)**	**32**	**(4.2)**	**190**	**(41.5)**	**17**	**(3.7)**	**610**	**(37.9)**	**67**	**(4.2)**
Presyncope	4	(1.0)	1	(0.3)	4	(0.5)	0	(0.0)	5	(1.1)	0	(0.0)	13	(0.8)	1	(0.1)
Radiculopathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Restless legs syndrome	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Sciatica	2	(0.5)	0	(0.0)	12	(1.6)	1	(0.1)	4	(0.9)	0	(0.0)	18	(1.1)	1	(0.1)
Seizure	4	(1.0)	1	(0.3)	10	(1.3)	5	(0.7)	6	(1.3)	2	(0.4)	20	(1.2)	8	(0.5)
Sensory disturbance	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Sensory loss	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sinus headache	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Somnolence	3	(0.8)	0	(0.0)	5	(0.7)	0	(0.0)	3	(0.7)	0	(0.0)	11	(0.7)	0	(0.0)
Spinal cord compression	2	(0.5)	2	(0.5)	4	(0.5)	3	(0.4)	4	(0.9)	4	(0.9)	10	(0.6)	9	(0.6)
Syncope	5	(1.3)	3	(0.8)	6	(0.8)	2	(0.3)	7	(1.5)	3	(0.7)	18	(1.1)	8	(0.5)
Tension headache	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Transient ischaemic attack	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Tremor	5	(1.3)	0	(0.0)	8	(1.0)	0	(0.0)	5	(1.1)	0	(0.0)	18	(1.1)	0	(0.0)
Trigeminal neuralgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
VIIth nerve paralysis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vasogenic cerebral oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**140**	**(36.6)**	**18**	**(4.7)**	**280**	**(36.4)**	**32**	**(4.2)**	**190**	**(41.5)**	**17**	**(3.7)**	**610**	**(37.9)**	**67**	**(4.2)**
Visual field defect	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Psychiatric disorders	**66**	**(17.3)**	**8**	**(2.1)**	**139**	**(18.1)**	**2**	**(0.3)**	**90**	**(19.7)**	**3**	**(0.7)**	**295**	**(18.3)**	**13**	**(0.8)**
Adjustment disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Adjustment disorder with depressed mood	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Affect lability	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Affective disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Agitation	4	(1.0)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	10	(0.6)	0	(0.0)
Anhedonia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Anxiety	13	(3.4)	0	(0.0)	37	(4.8)	0	(0.0)	25	(5.5)	1	(0.2)	75	(4.7)	1	(0.1)
Claustrophobia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Completed suicide	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Confusional state	8	(2.1)	4	(1.0)	16	(2.1)	0	(0.0)	12	(2.6)	1	(0.2)	36	(2.2)	5	(0.3)
Delirium	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Depressed mood	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Depression	9	(2.4)	0	(0.0)	27	(3.5)	1	(0.1)	19	(4.1)	0	(0.0)	55	(3.4)	1	(0.1)
Disorientation	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Dysphoria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Food aversion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric disorders	**66**	**(17.3)**	**8**	**(2.1)**	**139**	**(18.1)**	**2**	**(0.3)**	**90**	**(19.7)**	**3**	**(0.7)**	**295**	**(18.3)**	**13**	**(0.8)**
Hallucination	1	(0.3)	1	(0.3)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	1	(0.1)
Hallucination, auditory	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hallucination, visual	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Insomnia	32	(8.4)	1	(0.3)	58	(7.5)	0	(0.0)	38	(8.3)	1	(0.2)	128	(8.0)	2	(0.1)
Irritability	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Libido decreased	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Mental status changes	2	(0.5)	2	(0.5)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	2	(0.1)
Middle insomnia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Mood altered	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Mood swings	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Nervousness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Nightmare	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Panic attack	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Personality change	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Phobia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Psychosomatic disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Psychotic disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Restlessness	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sleep disorder	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric disorders	**66**	**(17.3)**	**8**	**(2.1)**	**139**	**(18.1)**	**2**	**(0.3)**	**90**	**(19.7)**	**3**	**(0.7)**	**295**	**(18.3)**	**13**	**(0.8)**
Stress	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Suicidal ideation	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Tension	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Trance	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Renal and urinary disorders	**31**	**(8.1)**	**1**	**(0.3)**	**70**	**(9.1)**	**6**	**(0.8)**	**54**	**(11.8)**	**9**	**(2.0)**	**155**	**(9.6)**	**16**	**(1.0)**
Acute kidney injury	3	(0.8)	0	(0.0)	11	(1.4)	2	(0.3)	8	(1.7)	5	(1.1)	22	(1.4)	7	(0.4)
Azotaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Chromaturia	3	(0.8)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	9	(0.6)	0	(0.0)
Chronic kidney disease	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	1	(0.2)	4	(0.2)	1	(0.1)
Dysuria	3	(0.8)	0	(0.0)	10	(1.3)	0	(0.0)	12	(2.6)	0	(0.0)	25	(1.6)	0	(0.0)
Haematuria	3	(0.8)	0	(0.0)	7	(0.9)	0	(0.0)	8	(1.7)	0	(0.0)	18	(1.1)	0	(0.0)
Hydronephrosis	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Hypertonic bladder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Incontinence	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Micturition urgency	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Nephrolithiasis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	4	(0.9)	0	(0.0)	6	(0.4)	0	(0.0)
Nocturia	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Obstructive uropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pneumaturia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**31**	**(8.1)**	**1**	**(0.3)**	**70**	**(9.1)**	**6**	**(0.8)**	**54**	**(11.8)**	**9**	**(2.0)**	**155**	**(9.6)**	**16**	**(1.0)**
Pollakiuria	3	(0.8)	0	(0.0)	16	(2.1)	0	(0.0)	12	(2.6)	0	(0.0)	31	(1.9)	0	(0.0)
Postrenal failure	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Proteinuria	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Renal colic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Renal cyst	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Renal failure	3	(0.8)	0	(0.0)	9	(1.2)	4	(0.5)	4	(0.9)	3	(0.7)	16	(1.0)	7	(0.4)
Renal impairment	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Renal infarct	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Renal pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tubulointerstitial nephritis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Urinary hesitation	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Urinary incontinence	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	4	(0.9)	0	(0.0)	12	(0.7)	0	(0.0)
Urinary retention	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Urinary tract disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Urinary tract pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Urine flow decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Urine odour abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Reproductive system and breast disorders	**26**	**(6.8)**	**2**	**(0.5)**	**39**	**(5.1)**	**1**	**(0.1)**	**23**	**(5.0)**	**0**	**(0.0)**	**88**	**(5.5)**	**3**	**(0.2)**
Amenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Atrophic vulvovaginitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Balanoposthitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Benign prostatic hyperplasia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Breast cyst	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Breast haematoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Breast pain	3	(0.8)	0	(0.0)	6	(0.8)	0	(0.0)	1	(0.2)	0	(0.0)	10	(0.6)	0	(0.0)
Breast swelling	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Breast tenderness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dysmenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erectile dysfunction	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Genital discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Genital haemorrhage	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Genital rash	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Gynaecomastia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Haematospermia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Menopausal symptoms	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Menorrhagia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Reproductive system and breast disorders	**26**	**(6.8)**	**2**	**(0.5)**	**39**	**(5.1)**	**1**	**(0.1)**	**23**	**(5.0)**	**0**	**(0.0)**	**88**	**(5.5)**	**3**	**(0.2)**
Menstruation irregular	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Metrorrhagia	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.4)	0	(0.0)	4	(0.2)	1	(0.1)
Nipple pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Nipple swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oedema genital	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pelvic pain	6	(1.6)	2	(0.5)	7	(0.9)	0	(0.0)	5	(1.1)	0	(0.0)	18	(1.1)	2	(0.1)
Penile erythema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Prostatic obstruction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Prostatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pruritus genital	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Scrotal erythema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Scrotal oedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Scrotal pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sexual dysfunction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Testicular atrophy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Testicular pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vaginal discharge	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Vaginal haemorrhage	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	7	(0.4)	0	(0.0)
Vulval disorder	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Reproductive system and breast disorders	**26**	**(6.8)**	**2**	**(0.5)**	**39**	**(5.1)**	**1**	**(0.1)**	**23**	**(5.0)**	**0**	**(0.0)**	**88**	**(5.5)**	**3**	**(0.2)**
Vulvar erosion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vulvovaginal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Vulvovaginal dryness	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Vulvovaginal pain	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Vulvovaginal pruritus	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**165**	**(43.2)**	**21**	**(5.5)**	**321**	**(41.7)**	**43**	**(5.6)**	**207**	**(45.2)**	**15**	**(3.3)**	**693**	**(43.1)**	**79**	**(4.9)**
Acute respiratory failure	2	(0.5)	1	(0.3)	1	(0.1)	0	(0.0)	1	(0.2)	1	(0.2)	4	(0.2)	2	(0.1)
Allergic cough	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Asthma	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Atelectasis	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Bronchial hyperreactivity	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Bronchial obstruction	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**165**	**(43.2)**	**21**	**(5.5)**	**321**	**(41.7)**	**43**	**(5.6)**	**207**	**(45.2)**	**15**	**(3.3)**	**693**	**(43.1)**	**79**	**(4.9)**
Bronchiectasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bronchospasm	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Choking sensation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Chronic obstructive pulmonary disease	3	(0.8)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	5	(0.3)	1	(0.1)
Cough	82	(21.5)	1	(0.3)	156	(20.3)	0	(0.0)	99	(21.6)	1	(0.2)	337	(20.9)	2	(0.1)
Diaphragmatic disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dry throat	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Dysaesthesia pharynx	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dysphonia	4	(1.0)	1	(0.3)	16	(2.1)	1	(0.1)	7	(1.5)	0	(0.0)	27	(1.7)	2	(0.1)
Dyspnoea	50	(13.1)	7	(1.8)	120	(15.6)	20	(2.6)	67	(14.6)	3	(0.7)	237	(14.7)	30	(1.9)
Dyspnoea at rest	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dyspnoea exertional	13	(3.4)	1	(0.3)	14	(1.8)	1	(0.1)	12	(2.6)	0	(0.0)	39	(2.4)	2	(0.1)
Epistaxis	9	(2.4)	1	(0.3)	11	(1.4)	1	(0.1)	9	(2.0)	0	(0.0)	29	(1.8)	2	(0.1)
Haemoptysis	6	(1.6)	1	(0.3)	11	(1.4)	3	(0.4)	3	(0.7)	0	(0.0)	20	(1.2)	4	(0.2)
Hiccups	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	6	(1.3)	1	(0.2)	9	(0.6)	1	(0.1)
Hyperventilation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**165**	**(43.2)**	**21**	**(5.5)**	**321**	**(41.7)**	**43**	**(5.6)**	**207**	**(45.2)**	**15**	**(3.3)**	**693**	**(43.1)**	**79**	**(4.9)**
Hypoxia	1	(0.3)	0	(0.0)	7	(0.9)	2	(0.3)	4	(0.9)	1	(0.2)	12	(0.7)	3	(0.2)
Increased bronchial secretion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Increased upper airway secretion	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Increased viscosity of nasal secretion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Interstitial lung disease	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Laryngeal discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Laryngeal inflammation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Laryngeal pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lung consolidation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)
Lung disorder	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lung infiltration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Nasal congestion	14	(3.7)	0	(0.0)	23	(3.0)	0	(0.0)	15	(3.3)	0	(0.0)	52	(3.2)	0	(0.0)
Nasal discomfort	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Nasal disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Nasal dryness	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**165**	**(43.2)**	**21**	**(5.5)**	**321**	**(41.7)**	**43**	**(5.6)**	**207**	**(45.2)**	**15**	**(3.3)**	**693**	**(43.1)**	**79**	**(4.9)**
Nasal inflammation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nasal mucosal disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Nasal obstruction	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Nasal ulcer	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oropharyngeal discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oropharyngeal pain	13	(3.4)	0	(0.0)	25	(3.3)	0	(0.0)	23	(5.0)	0	(0.0)	61	(3.8)	0	(0.0)
Orthopnoea	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Painful respiration	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Paranasal sinus discomfort	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Pharyngeal oedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pleural effusion	9	(2.4)	6	(1.6)	14	(1.8)	6	(0.8)	11	(2.4)	2	(0.4)	34	(2.1)	14	(0.9)
Pleurisy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pleuritic pain	3	(0.8)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	1	(0.2)	8	(0.5)	1	(0.1)
Pneumonia aspiration	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	0	(0.0)	3	(0.2)	1	(0.1)
Pneumonitis	6	(1.6)	1	(0.3)	17	(2.2)	3	(0.4)	8	(1.7)	1	(0.2)	31	(1.9)	5	(0.3)
Pneumothorax	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	1	(0.2)	5	(0.3)	1	(0.1)
Productive cough	18	(4.7)	0	(0.0)	25	(3.3)	0	(0.0)	14	(3.1)	0	(0.0)	57	(3.5)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**165**	**(43.2)**	**21**	**(5.5)**	**321**	**(41.7)**	**43**	**(5.6)**	**207**	**(45.2)**	**15**	**(3.3)**	**693**	**(43.1)**	**79**	**(4.9)**
Pulmonary congestion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Pulmonary embolism	3	(0.8)	3	(0.8)	9	(1.2)	8	(1.0)	7	(1.5)	3	(0.7)	19	(1.2)	14	(0.9)
Pulmonary haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Pulmonary hypertension	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pulmonary infarction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Pulmonary oedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Pulmonary thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	1	(0.2)	2	(0.1)	2	(0.1)
Rales	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Respiratory disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Respiratory distress	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Respiratory failure	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	2	(0.4)	4	(0.2)	2	(0.1)
Respiratory tract congestion	0	(0.0)	0	(0.0)	6	(0.8)	0	(0.0)	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**165**	**(43.2)**	**21**	**(5.5)**	**321**	**(41.7)**	**43**	**(5.6)**	**207**	**(45.2)**	**15**	**(3.3)**	**693**	**(43.1)**	**79**	**(4.9)**
Respiratory tract haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Rhinitis allergic	5	(1.3)	0	(0.0)	13	(1.7)	0	(0.0)	5	(1.1)	0	(0.0)	23	(1.4)	0	(0.0)
Rhinorrhoea	8	(2.1)	0	(0.0)	4	(0.5)	0	(0.0)	14	(3.1)	0	(0.0)	26	(1.6)	0	(0.0)
Sinus congestion	8	(2.1)	0	(0.0)	10	(1.3)	0	(0.0)	5	(1.1)	0	(0.0)	23	(1.4)	0	(0.0)
Sleep apnoea syndrome	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Sneezing	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Tachypnoea	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Throat irritation	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Tonsillar disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Upper-airway cough syndrome	5	(1.3)	0	(0.0)	9	(1.2)	0	(0.0)	6	(1.3)	0	(0.0)	20	(1.2)	0	(0.0)
Wheezing	2	(0.5)	0	(0.0)	12	(1.6)	0	(0.0)	8	(1.7)	0	(0.0)	22	(1.4)	0	(0.0)
Skin and subcutaneous tissue disorders	**212**	**(55.5)**	**5**	**(1.3)**	**444**	**(57.7)**	**10**	**(1.3)**	**270**	**(59.0)**	**7**	**(1.5)**	**926**	**(57.6)**	**22**	**(1.4)**
Acne	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	8	(0.5)	0	(0.0)
Actinic keratosis	1	(0.3)	0	(0.0)	6	(0.8)	0	(0.0)	6	(1.3)	0	(0.0)	13	(0.8)	0	(0.0)
Alopecia	10	(2.6)	0	(0.0)	15	(2.0)	0	(0.0)	9	(2.0)	0	(0.0)	34	(2.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**212**	**(55.5)**	**5**	**(1.3)**	**444**	**(57.7)**	**10**	**(1.3)**	**270**	**(59.0)**	**7**	**(1.5)**	**926**	**(57.6)**	**22**	**(1.4)**
Angioedema	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blister	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Cold sweat	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Decubitus ulcer	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	8	(0.5)	0	(0.0)
Dermatitis	1	(0.3)	0	(0.0)	6	(0.8)	0	(0.0)	4	(0.9)	0	(0.0)	11	(0.7)	0	(0.0)
Dermatitis acneiform	5	(1.3)	0	(0.0)	6	(0.8)	0	(0.0)	3	(0.7)	0	(0.0)	14	(0.9)	0	(0.0)
Dermatitis allergic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Dermatitis atopic	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis bullous	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis contact	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	4	(0.9)	0	(0.0)	7	(0.4)	0	(0.0)
Dermatitis exfoliative	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis psoriasiform	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Diffuse alopecia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Drug eruption	2	(0.5)	1	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	1	(0.1)
Dry skin	27	(7.1)	0	(0.0)	46	(6.0)	0	(0.0)	24	(5.2)	0	(0.0)	97	(6.0)	0	(0.0)
Dyshidrotic eczema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Ecchymosis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Eczema	6	(1.6)	0	(0.0)	16	(2.1)	0	(0.0)	8	(1.7)	0	(0.0)	30	(1.9)	0	(0.0)
Eczema asteatotic	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**212**	**(55.5)**	**5**	**(1.3)**	**444**	**(57.7)**	**10**	**(1.3)**	**270**	**(59.0)**	**7**	**(1.5)**	**926**	**(57.6)**	**22**	**(1.4)**
Eczema nummular	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erythema	15	(3.9)	1	(0.3)	26	(3.4)	0	(0.0)	23	(5.0)	0	(0.0)	64	(4.0)	1	(0.1)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Erythema nodosum	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Excessive granulation tissue	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Exfoliative rash	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Granuloma skin	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Haemorrhage subcutaneous	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hair colour changes	4	(1.0)	0	(0.0)	4	(0.5)	0	(0.0)	10	(2.2)	0	(0.0)	18	(1.1)	0	(0.0)
Hair disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hair growth abnormal	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Hair texture abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Hyperhidrosis	9	(2.4)	0	(0.0)	18	(2.3)	0	(0.0)	9	(2.0)	0	(0.0)	36	(2.2)	0	(0.0)
Hyperkeratosis	0	(0.0)	0	(0.0)	6	(0.8)	0	(0.0)	7	(1.5)	0	(0.0)	13	(0.8)	0	(0.0)
Hypertrichosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ichthyosis acquired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Ingrowing nail	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**212**	**(55.5)**	**5**	**(1.3)**	**444**	**(57.7)**	**10**	**(1.3)**	**270**	**(59.0)**	**7**	**(1.5)**	**926**	**(57.6)**	**22**	**(1.4)**
Intertrigo	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Keratosis pilaris	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	2	(0.1)	1	(0.1)
Lichen sclerosus	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Lichenification	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lichenoid keratosis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Linear IgA disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Macule	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Madarosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Melanocytic hyperplasia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Miliaria	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Nail discolouration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nail disorder	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Nail dystrophy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nail growth abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neurodermatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Neutrophilic dermatosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Night sweats	15	(3.9)	0	(0.0)	29	(3.8)	0	(0.0)	20	(4.4)	0	(0.0)	64	(4.0)	0	(0.0)
Onychoclasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**212**	**(55.5)**	**5**	**(1.3)**	**444**	**(57.7)**	**10**	**(1.3)**	**270**	**(59.0)**	**7**	**(1.5)**	**926**	**(57.6)**	**22**	**(1.4)**
Pain of skin	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Palmar erythema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Panniculitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Papule	3	(0.8)	0	(0.0)	9	(1.2)	0	(0.0)	5	(1.1)	0	(0.0)	17	(1.1)	0	(0.0)
Parapsoriasis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Penile ulceration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Petechiae	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Photosensitivity reaction	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	4	(0.9)	0	(0.0)	12	(0.7)	0	(0.0)
Pigmentation disorder	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Prurigo	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Pruritus	97	(25.4)	0	(0.0)	188	(24.4)	2	(0.3)	105	(22.9)	2	(0.4)	390	(24.2)	4	(0.2)
Pruritus allergic	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pruritus generalised	3	(0.8)	0	(0.0)	10	(1.3)	0	(0.0)	4	(0.9)	0	(0.0)	17	(1.1)	0	(0.0)
Pseudofolliculitis barbae	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Psoriasis	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)	3	(0.7)	1	(0.2)	8	(0.5)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**212**	**(55.5)**	**5**	**(1.3)**	**444**	**(57.7)**	**10**	**(1.3)**	**270**	**(59.0)**	**7**	**(1.5)**	**926**	**(57.6)**	**22**	**(1.4)**
Purpura	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Pustular psoriasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rash	68	(17.8)	0	(0.0)	151	(19.6)	2	(0.3)	91	(19.9)	1	(0.2)	310	(19.3)	3	(0.2)
Rash erythematous	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)	8	(1.7)	1	(0.2)	13	(0.8)	1	(0.1)
Rash follicular	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Rash generalised	3	(0.8)	0	(0.0)	9	(1.2)	2	(0.3)	4	(0.9)	0	(0.0)	16	(1.0)	2	(0.1)
Rash macular	3	(0.8)	0	(0.0)	6	(0.8)	0	(0.0)	4	(0.9)	0	(0.0)	13	(0.8)	0	(0.0)
Rash maculo-papular	23	(6.0)	1	(0.3)	34	(4.4)	3	(0.4)	18	(3.9)	0	(0.0)	75	(4.7)	4	(0.2)
Rash papular	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	1	(0.2)	0	(0.0)	9	(0.6)	0	(0.0)
Rash pruritic	3	(0.8)	0	(0.0)	10	(1.3)	0	(0.0)	9	(2.0)	1	(0.2)	22	(1.4)	1	(0.1)
Rash vesicular	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Rosacea	3	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Scab	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Scar pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sebaceous gland disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Seborrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Seborrhoeic dermatitis	3	(0.8)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Skin burning sensation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**212**	**(55.5)**	**5**	**(1.3)**	**444**	**(57.7)**	**10**	**(1.3)**	**270**	**(59.0)**	**7**	**(1.5)**	**926**	**(57.6)**	**22**	**(1.4)**
Skin depigmentation	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Skin discolouration	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Skin disorder	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Skin exfoliation	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Skin fissures	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	3	(0.2)	0	(0.0)
Skin haemorrhage	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Skin hyperpigmentation	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Skin hypopigmentation	6	(1.6)	0	(0.0)	15	(2.0)	0	(0.0)	8	(1.7)	0	(0.0)	29	(1.8)	0	(0.0)
Skin induration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin irritation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Skin lesion	8	(2.1)	0	(0.0)	18	(2.3)	0	(0.0)	8	(1.7)	0	(0.0)	34	(2.1)	0	(0.0)
Skin maceration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Skin mass	5	(1.3)	1	(0.3)	4	(0.5)	0	(0.0)	3	(0.7)	0	(0.0)	12	(0.7)	1	(0.1)
Skin plaque	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Skin striae	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin ulcer	3	(0.8)	0	(0.0)	7	(0.9)	0	(0.0)	3	(0.7)	0	(0.0)	13	(0.8)	0	(0.0)
Solar dermatitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**212**	**(55.5)**	**5**	**(1.3)**	**444**	**(57.7)**	**10**	**(1.3)**	**270**	**(59.0)**	**7**	**(1.5)**	**926**	**(57.6)**	**22**	**(1.4)**
Stasis dermatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Stevens-Johnson syndrome	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Swelling face	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Toxic skin eruption	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Transient acantholytic dermatosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Urticaria	2	(0.5)	0	(0.0)	5	(0.7)	0	(0.0)	3	(0.7)	0	(0.0)	10	(0.6)	0	(0.0)
Urticaria papular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Vitiligo	32	(8.4)	0	(0.0)	75	(9.8)	0	(0.0)	50	(10.9)	0	(0.0)	157	(9.8)	0	(0.0)
Xanthelasma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Xeroderma	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Surgical and medical procedures	**1**	**(0.3)**	**1**	**(0.3)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.1)**	**1**	**(0.1)**
Skin neoplasm excision	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Vascular disorders	**39**	**(10.2)**	**8**	**(2.1)**	**111**	**(14.4)**	**12**	**(1.6)**	**76**	**(16.6)**	**17**	**(3.7)**	**226**	**(14.0)**	**37**	**(2.3)**
Aortic stenosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**39**	**(10.2)**	**8**	**(2.1)**	**111**	**(14.4)**	**12**	**(1.6)**	**76**	**(16.6)**	**17**	**(3.7)**	**226**	**(14.0)**	**37**	**(2.3)**
Deep vein thrombosis	4	(1.0)	2	(0.5)	7	(0.9)	0	(0.0)	5	(1.1)	3	(0.7)	16	(1.0)	5	(0.3)
Embolism	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Embolism venous	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Flushing	0	(0.0)	0	(0.0)	10	(1.3)	0	(0.0)	6	(1.3)	0	(0.0)	16	(1.0)	0	(0.0)
Haematoma	1	(0.3)	0	(0.0)	6	(0.8)	0	(0.0)	3	(0.7)	1	(0.2)	10	(0.6)	1	(0.1)
Haemorrhage	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Hot flush	8	(2.1)	0	(0.0)	12	(1.6)	0	(0.0)	12	(2.6)	0	(0.0)	32	(2.0)	0	(0.0)
Hypertension	7	(1.8)	1	(0.3)	31	(4.0)	7	(0.9)	19	(4.1)	9	(2.0)	57	(3.5)	17	(1.1)
Hypertensive crisis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Hypotension	8	(2.1)	2	(0.5)	19	(2.5)	0	(0.0)	8	(1.7)	2	(0.4)	35	(2.2)	4	(0.2)
Intermittent claudication	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Intra-abdominal haematoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Ischaemia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Jugular vein thrombosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphatic fistula	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphoedema	4	(1.0)	0	(0.0)	14	(1.8)	0	(0.0)	8	(1.7)	0	(0.0)	26	(1.6)	0	(0.0)
Orthostatic hypotension	0	(0.0)	0	(0.0)	6	(0.8)	3	(0.4)	1	(0.2)	0	(0.0)	7	(0.4)	3	(0.2)
Pallor	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	3	(0.2)	0	(0.0)
Peripheral coldness	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**39**	**(10.2)**	**8**	**(2.1)**	**111**	**(14.4)**	**12**	**(1.6)**	**76**	**(16.6)**	**17**	**(3.7)**	**226**	**(14.0)**	**37**	**(2.3)**
Peripheral embolism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral ischaemia	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Peripheral venous disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Phlebitis	1	(0.3)	1	(0.3)	2	(0.3)	1	(0.1)	2	(0.4)	0	(0.0)	5	(0.3)	2	(0.1)
Poor venous access	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Raynaud's phenomenon	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Subclavian vein thrombosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Superior vena cava occlusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Superior vena cava syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Thrombophlebitis superficial	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Varicophlebitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vasculitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vein disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Vena cava thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Venous thrombosis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-15 有害事象（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
NULL	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(0.3)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(0.1)**	**0**	**(0.0)**
NULL	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

Every subject is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.
Grades are based on NCI CTCAE version 4.0.
Adverse event terms are from MedDRA Version 18.0.
(MK-3475 KN-001 Database Cutoff Date: [redacted]).
(MK-3475 KN-002 Database Cutoff Date: 12MAY2014).
(MK-3475 KN-006 Database Cutoff Date: 03SEP2014).
(MK-3475 KN-041 Database Cutoff Date: [redacted]).

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Abdominal discomfort	Abdominal discomfort
	Abdominal distension	Abdominal distension
	Abdominal mass	Abdominal mass
	Abdominal neoplasm	Abdominal neoplasm
	Abdominal pain	Abdominal pain
	Abdominal pain lower	Abdominal pain lower
	Abdominal pain upper	Abdominal pain upper
	Abdominal rigidity	Abdominal rigidity
	Abdominal tenderness	Abdominal tenderness
	Abdominal wall abscess	Abdominal wall abscess
	Abnormal sensation in eye	Abnormal sensation in eye
	Abscess	Abscess
	Accessory spleen	Accessory spleen
	Accidental overdose	Accidental overdose
	Acidosis	Acidosis
	Acne	Acne
	Acrochordon	Acrochordon
	Actinic keratosis	Actinic keratosis
	Action tremor	Action tremor
	Activated partial thromboplastin time prolonged	Activated partial thromboplastin time prolonged
	Acute coronary syndrome	Acute coronary syndrome
	Acute myocardial infarction	Acute myocardial infarction
	Acute respiratory failure	Acute respiratory failure
	Acute tonsillitis	Acute tonsillitis
	Adenocarcinoma	Adenocarcinoma
	Adenocarcinoma gastric	Adenocarcinoma gastric
	Adjustment disorder	Adjustment disorder
	Adjustment disorder with depressed mood	Adjustment disorder with depressed mood
	Adrenal insufficiency	Adrenal insufficiency
	Adrenocortical insufficiency acute	Adrenocortical insufficiency acute
	Adverse drug reaction	Adverse drug reaction
	Aerophagia	Aerophagia
	Affect lability	Affect lability
	Affective disorder	Affective disorder
○	Age-related macular degeneration	Dry age-related macular degeneration
	Ageusia	Ageusia
	Agitation	Agitation
	Akathisia	Akathisia
	Alanine aminotransferase	Alanine aminotransferase
	Alanine aminotransferase decreased	Alanine aminotransferase decreased
	Alanine aminotransferase increased	Alanine aminotransferase increased
	Allergic cough	Allergic cough
	Allergy to animal	Allergy to animal
	Alopecia	Alopecia
	Altered state of consciousness	Altered state of consciousness
	Altered visual depth perception	Altered visual depth perception
	Amenorrhoea	Amenorrhoea
	Amnesia	Amnesia
	Amnestic disorder	Amnestic disorder
	Amylase increased	Amylase increased
	Amyotrophy	Amyotrophy
	Anaemia	Anaemia
	Anaemia of chronic disease	Anaemia of chronic disease
	Anal fistula	Anal fistula
	Anal pruritus	Anal pruritus
	Anaphylactic reaction	Anaphylactic reaction
	Anaphylactoid reaction	Anaphylactoid reaction
	Angina pectoris	Angina pectoris
	Angina unstable	Angina unstable
	Anhedonia	Anhedonia

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Ankylosing spondylitis	Ankylosing spondylitis
	Anorectal disorder	Anorectal disorder
	Anosmia	Anosmia
	Anxiety	Anxiety
	Aortic bruit	Aortic bruit
	Aortic stenosis	Aortic stenosis
	Aortic valve incompetence	Aortic valve incompetence
	Aortic valve stenosis	Aortic valve stenosis
	Aphasia	Aphasia
	Aphonia	Aphonia
	Aphthous stomatitis	Aphthous stomatitis
	Appendicitis perforated	Appendicitis perforated
	Aptyalism	Aptyalism
	Arrhythmia supraventricular	Arrhythmia supraventricular
	Arthralgia	Arthralgia
	Arthritis	Arthritis
	Arthropathy	Arthropathy
	Arthropod bite	Arthropod bite
	Ascites	Ascites
	Aspartate aminotransferase increased	Aspartate aminotransferase increased
	Asthenia	Asthenia
	Asthenopia	Asthenopia
	Asthma	Asthma
	Ataxia	Ataxia
	Atelectasis	Atelectasis
	Atopy	Atopy
	Atrial fibrillation	Atrial fibrillation
	Atrial flutter	Atrial flutter
	Atrial thrombosis	Atrial thrombosis
	Atrioventricular block first degree	Atrioventricular block first degree
	Atrophic vulvovaginitis	Atrophic vulvovaginitis
	Auriculotemporal syndrome	Auriculotemporal syndrome
	Autoantibody positive	Autoantibody positive
	Autoimmune disorder	Autoimmune disorder
	Autoimmune hepatitis	Autoimmune hepatitis
	Autoimmune pancreatitis	Autoimmune pancreatitis
	Autoimmune thyroiditis	Autoimmune thyroiditis
	Axillary mass	Axillary mass
	Axillary pain	Axillary pain
	Azotaemia	Azotaemia
	Back disorder	Back disorder
	Back injury	Back injury
	Back pain	Back pain
	Bacteraemia	Bacteraemia
	Bacterial sepsis	Bacterial sepsis
	Bacterial vaginosis	Bacterial vaginosis
	Balance disorder	Balance disorder
	Balanoposthitis	Balanoposthitis
	Barrett's oesophagus	Barrett's oesophagus
	Basal cell carcinoma	Basal cell carcinoma
	Basosquamous carcinoma	Basosquamous carcinoma
	Benign prostatic hyperplasia	Benign prostatic hyperplasia
	Bile duct obstruction	Bile duct obstruction
	Bile duct stone	Bile duct stone
	Bilirubin conjugated increased	Bilirubin conjugated increased
	Biopsy skin	Biopsy skin
	Blindness	Blindness
	Blister	Blister
	Blood albumin decreased	Blood albumin decreased
	Blood albumin increased	Blood albumin increased

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Blood alkaline phosphatase	Blood alkaline phosphatase
	Blood alkaline phosphatase decreased	Blood alkaline phosphatase decreased
	Blood alkaline phosphatase increased	Blood alkaline phosphatase increased
	Blood bicarbonate decreased	Blood bicarbonate decreased
	Blood bicarbonate increased	Blood bicarbonate increased
	Blood bilirubin	Blood bilirubin
	Blood bilirubin increased	Blood bilirubin increased
	Blood calcium decreased	Blood calcium decreased
	Blood calcium increased	Blood calcium increased
	Blood cholesterol increased	Blood cholesterol increased
	Blood corticotrophin decreased	Blood corticotrophin decreased
	Blood corticotrophin increased	Blood corticotrophin increased
	Blood cortisol decreased	Blood cortisol decreased
	Blood creatine phosphokinase increased	Blood creatine phosphokinase increased
	Blood creatinine increased	Blood creatinine increased
	Blood folate decreased	Blood folate decreased
	Blood glucose abnormal	Blood glucose abnormal
	Blood glucose increased	Blood glucose increased
	Blood immunoglobulin G decreased	Blood immunoglobulin G decreased
	Blood iron decreased	Blood iron decreased
	Blood lactate dehydrogenase increased	Blood lactate dehydrogenase increased
	Blood lactic acid increased	Blood lactic acid increased
	Blood luteinising hormone decreased	Blood luteinising hormone decreased
	Blood magnesium decreased	Blood magnesium decreased
	Blood parathyroid hormone increased	Blood parathyroid hormone increased
	Blood phosphorus decreased	Blood phosphorus decreased
	Blood phosphorus increased	Blood phosphorus increased
	Blood potassium decreased	Blood potassium decreased
	Blood potassium increased	Blood potassium increased
	Blood pressure diastolic increased	Blood pressure diastolic increased
	Blood sodium decreased	Blood sodium decreased
	Blood testosterone decreased	Blood testosterone decreased
	Blood testosterone increased	Blood testosterone increased
	Blood thyroid stimulating hormone decreased	Blood thyroid stimulating hormone decreased
	Blood thyroid stimulating hormone increased	Blood thyroid stimulating hormone increased
	Blood triglycerides increased	Blood triglycerides increased
	Blood urea increased	Blood urea increased
	Blood uric acid increased	Blood uric acid increased
	Blood urine present	Blood urine present
	Body temperature increased	Body temperature increased
	Body tinea	Body tinea
	Bone pain	Bone pain
	Bradycardia	Bradycardia
	Brain herniation	Brain herniation
	Brain natriuretic peptide increased	Brain natriuretic peptide increased
	Brain oedema	Brain oedema
	Breast cyst	Breast cyst
	Breast haematoma	Breast haematoma
	Breast pain	Breast pain
	Breast swelling	Breast swelling
	Breast tenderness	Breast tenderness
	Breath odour	Breath odour
	Breath sounds abnormal	Breath sounds abnormal
	Bronchial hyperreactivity	Bronchial hyperreactivity
	Bronchial obstruction	Bronchial obstruction
	Bronchiectasis	Bronchiectasis
	Bronchitis	Bronchitis
	Bronchospasm	Bronchospasm
	Bundle branch block left	Bundle branch block left
	Bundle branch block right	Bundle branch block right

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Burning sensation	Burning sensation
	Burns second degree	Burns second degree
	Bursa disorder	Bursa disorder
	Bursitis	Bursitis
	C-reactive protein increased	C-reactive protein increased
	Cachexia	Cachexia
	Cancer pain	Cancer pain
	Candida infection	Candida infection
	Cardiac aneurysm	Cardiac aneurysm
	Cardiac arrest	Cardiac arrest
	Cardiac disorder	Cardiac disorder
	Cardiac failure	Cardiac failure
	Cardiac failure congestive	Cardiac failure congestive
	Cardiac murmur	Cardiac murmur
	Cardiac murmur functional	Cardiac murmur functional
	Cardiac ventricular disorder	Cardiac ventricular disorder
	Cardiac ventricular thrombosis	Cardiac ventricular thrombosis
	Cardiogenic shock	Cardiogenic shock
	Cardiomegaly	Cardiomegaly
	Carpal tunnel syndrome	Carpal tunnel syndrome
	Cataract	Cataract
	Catheter site infection	Catheter site infection
	Catheter site pain	Catheter site pain
	Catheter site rash	Catheter site rash
	Cell death	Cell death
	Cellulitis	Cellulitis
	Cerebellar syndrome	Cerebellar syndrome
	Cerebral haemangioma	Cerebral haemangioma
	Cerebral haemorrhage	Cerebral haemorrhage
	Cerebral infarction	Cerebral infarction
	Cerebrovascular accident	Cerebrovascular accident
	Cerumen impaction	Cerumen impaction
	Chalazion	Chalazion
	Chapped lips	Chapped lips
	Cheilitis	Cheilitis
	Chest discomfort	Chest discomfort
	Chest pain	Chest pain
	Chillblains	Chillblains
	Chills	Chills
	Choking sensation	Choking sensation
	Cholangitis	Cholangitis
	Cholecystitis	Cholecystitis
	Cholecystitis acute	Cholecystitis acute
	Cholestasis	Cholestasis
	Chondrocalcinosis pyrophosphate	Chondrocalcinosis pyrophosphate
	Chromaturia	Chromaturia
	Chronic obstructive pulmonary disease	Chronic obstructive pulmonary disease
	Chronic sinusitis	Chronic sinusitis
	Ciliary muscle spasm	Ciliary muscle spasm
	Claustrophobia	Claustrophobia
	Clavicle fracture	Clavicle fracture
	Clostridium difficile colitis	Clostridium difficile colitis
	Clostridium difficile infection	Clostridium difficile infection
	Coagulopathy	Coagulopathy
	Coccydynia	Coccydynia
	Cognitive disorder	Cognitive disorder
	Cold sweat	Cold sweat
	Colitis	Colitis
	Colitis microscopic	Colitis microscopic
	Completed suicide	Completed suicide

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Computerised tomogram thorax abnormal	Computerised tomogram thorax abnormal
	Concussion	Concussion
	Confusional state	Confusional state
	Congestive cardiomyopathy	Congestive cardiomyopathy
	Conjunctival haemorrhage	Conjunctival haemorrhage
	Conjunctival hyperaemia	Conjunctival hyperaemia
	Conjunctivitis	Conjunctivitis
	Conjunctivitis allergic	Conjunctivitis allergic
	Constipation	Constipation
	Contrast media allergy	Contrast media allergy
	Contrast media reaction	Contrast media reaction
	Contusion	Contusion
○	Convulsion	Seizure
	Coordination abnormal	Coordination abnormal
	Corneal abrasion	Corneal abrasion
	Corneal pigmentation	Corneal pigmentation
	Coronary artery disease	Coronary artery disease
	Cortisol free urine decreased	Cortisol free urine decreased
	Costochondritis	Costochondritis
	Cough	Cough
	Cow's milk intolerance	Cow's milk intolerance
	Creatinine renal clearance increased	Creatinine renal clearance increased
	Crepitations	Crepitations
	Cushingoid	Cushingoid
	Cyanosis	Cyanosis
	Cyst	Cyst
	Cystitis	Cystitis
	Cytokine release syndrome	Cytokine release syndrome
	Cytomegalovirus colitis	Cytomegalovirus colitis
	Deafness	Deafness
	Deafness unilateral	Deafness unilateral
	Death	Death
	Decreased appetite	Decreased appetite
	Decubitus ulcer	Decubitus ulcer
	Deep vein thrombosis	Deep vein thrombosis
	Defaecation urgency	Defaecation urgency
	Dehydration	Dehydration
	Delirium	Delirium
	Dental caries	Dental caries
	Depressed level of consciousness	Depressed level of consciousness
	Depressed mood	Depressed mood
	Depression	Depression
	Dermatitis	Dermatitis
	Dermatitis acneiform	Dermatitis acneiform
	Dermatitis allergic	Dermatitis allergic
	Dermatitis atopic	Dermatitis atopic
	Dermatitis bullous	Dermatitis bullous
	Dermatitis contact	Dermatitis contact
	Dermatitis exfoliative	Dermatitis exfoliative
	Dermatitis psoriasiform	Dermatitis psoriasiform
	Dermatophytosis	Dermatophytosis
	Desmoplastic melanoma	Desmoplastic melanoma
	Developmental coordination disorder	Developmental coordination disorder
	Device breakage	Device breakage
	Device dislocation	Device dislocation
	Device failure	Device failure
	Device occlusion	Device occlusion
	Device related infection	Device related infection
	Diabetes mellitus	Diabetes mellitus
	Diabetes mellitus inadequate control	Diabetes mellitus inadequate control

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Diabetic ketoacidosis	Diabetic ketoacidosis
	Diaphragmatic disorder	Diaphragmatic disorder
	Diarrhoea	Diarrhoea
	Diffuse alopecia	Diffuse alopecia
	Diplopia	Diplopia
	Discomfort	Discomfort
	Disorientation	Disorientation
	Disseminated intravascular coagulation	Disseminated intravascular coagulation
	Disturbance in attention	Disturbance in attention
	Diverticulitis	Diverticulitis
	Diverticulitis intestinal haemorrhagic	Diverticulitis intestinal haemorrhagic
	Diverticulum	Diverticulum
	Dizziness	Dizziness
	Dizziness postural	Dizziness postural
	Drug eruption	Drug eruption
	Drug hypersensitivity	Drug hypersensitivity
	Drug-induced liver injury	Drug-induced liver injury
	Dry eye	Dry eye
	Dry mouth	Dry mouth
	Dry skin	Dry skin
	Dry throat	Dry throat
	Duodenal ulcer	Duodenal ulcer
	Duodenitis	Duodenitis
	Duodenogastric reflux	Duodenogastric reflux
	Dysaesthesia	Dysaesthesia
	Dysaesthesia pharynx	Dysaesthesia pharynx
	Dysarthria	Dysarthria
	Dysgeusia	Dysgeusia
	Dyshidrotic eczema	Dyshidrotic eczema
	Dyskinesia	Dyskinesia
	Dysmenorrhoea	Dysmenorrhoea
	Dyspepsia	Dyspepsia
	Dysphagia	Dysphagia
	Dysphonia	Dysphonia
	Dysphoria	Dysphoria
	Dyspnoea	Dyspnoea
	Dyspnoea at rest	Dyspnoea at rest
	Dyspnoea exertional	Dyspnoea exertional
	Dysuria	Dysuria
	Ear abrasion	Ear abrasion
	Ear discomfort	Ear discomfort
	Ear haemorrhage	Ear haemorrhage
	Ear infection	Ear infection
	Ear infection fungal	Ear infection fungal
	Ear pain	Ear pain
	Ear swelling	Ear swelling
	Early satiety	Early satiety
	Ecchymosis	Ecchymosis
	Ectropion	Ectropion
	Eczema	Eczema
	Eczema asteatotic	Eczema asteatotic
	Eczema eyelids	Eczema eyelids
	Eczema nummular	Eczema nummular
	Electrocardiogram QT prolonged	Electrocardiogram QT prolonged
	Electrocardiogram ST segment abnormal	Electrocardiogram ST segment abnormal
	Electrocardiogram T wave inversion	Electrocardiogram T wave inversion
	Electrocardiogram abnormal	Electrocardiogram abnormal
	Electrocardiogram change	Electrocardiogram change
	Electrocardiogram low voltage	Electrocardiogram low voltage
	Electrocardiogram repolarisation abnormality	Electrocardiogram repolarisation abnormality

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Electrolyte imbalance	Electrolyte imbalance
	Embolism	Embolism
	Embolism venous	Embolism venous
	Encephalitis	Encephalitis
	Encephalopathy	Encephalopathy
	Endocrine disorder	Endocrine disorder
	Enteritis	Enteritis
	Enterocolitis	Enterocolitis
	Enterocolitis infectious	Enterocolitis infectious
	Entropion	Entropion
	Eosinophil count increased	Eosinophil count increased
	Eosinophilia	Eosinophilia
	Epigastric discomfort	Epigastric discomfort
	Epilepsy	Epilepsy
	Epistaxis	Epistaxis
	Erectile dysfunction	Erectile dysfunction
	Eructation	Eructation
	Erysipelas	Erysipelas
	Erythema	Erythema
	Erythema migrans	Erythema migrans
	Erythema multiforme	Erythema multiforme
	Erythema nodosum	Erythema nodosum
	Erythema of eyelid	Erythema of eyelid
	Erythrasma	Erythrasma
	Eschar	Eschar
	Escherichia bacteraemia	Escherichia bacteraemia
	Escherichia urinary tract infection	Escherichia urinary tract infection
	Excessive granulation tissue	Excessive granulation tissue
	Excoriation	Excoriation
	Exercise tolerance decreased	Exercise tolerance decreased
	Exfoliative rash	Exfoliative rash
	Exostosis	Exostosis
	External ear inflammation	External ear inflammation
	External ear pain	External ear pain
	Eye disorder	Eye disorder
	Eye infection	Eye infection
	Eye inflammation	Eye inflammation
	Eye irritation	Eye irritation
	Eye movement disorder	Eye movement disorder
	Eye pain	Eye pain
	Eye pruritus	Eye pruritus
	Eye swelling	Eye swelling
	Eyelash discolouration	Eyelash discolouration
	Eyelid disorder	Eyelid disorder
	Eyelid exfoliation	Eyelid exfoliation
	Eyelid function disorder	Eyelid function disorder
	Eyelid oedema	Eyelid oedema
	Eyelid ptosis	Eyelid ptosis
	Eyelid rash	Eyelid rash
	Eyelids pruritus	Eyelids pruritus
	Face injury	Face injury
	Face oedema	Face oedema
	Facial bones fracture	Facial bones fracture
	Facial nerve disorder	Facial nerve disorder
	Facial pain	Facial pain
	Faecal incontinence	Faecal incontinence
	Faeces discoloured	Faeces discoloured
	Faeces hard	Faeces hard
	Faeces pale	Faeces pale
	Faeces soft	Faeces soft

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Failure to thrive	Failure to thrive
	Fall	Fall
	Fatigue	Fatigue
	Febrile infection	Febrile infection
	Feeling abnormal	Feeling abnormal
	Feeling cold	Feeling cold
	Feeling drunk	Feeling drunk
	Feeling hot	Feeling hot
	Feeling jittery	Feeling jittery
	Femoral hernia	Femoral hernia
	Fibrin D dimer increased	Fibrin D dimer increased
	Fibromyalgia	Fibromyalgia
	Fistula	Fistula
	Flank pain	Flank pain
	Flatulence	Flatulence
	Fluid overload	Fluid overload
	Fluid retention	Fluid retention
	Flushing	Flushing
	Folliculitis	Folliculitis
	Food allergy	Food allergy
	Food aversion	Food aversion
	Food poisoning	Food poisoning
	Foot fracture	Foot fracture
	Foreign body sensation in eyes	Foreign body sensation in eyes
	Fracture pain	Fracture pain
	Frequent bowel movements	Frequent bowel movements
	Fungal infection	Fungal infection
	Fungal oesophagitis	Fungal oesophagitis
	Fungal skin infection	Fungal skin infection
	Furuncle	Furuncle
	Gait disturbance	Gait disturbance
	Gamma-glutamyltransferase decreased	Gamma-glutamyltransferase decreased
	Gamma-glutamyltransferase increased	Gamma-glutamyltransferase increased
	Gastric disorder	Gastric disorder
	Gastric ulcer haemorrhage	Gastric ulcer haemorrhage
	Gastritis	Gastritis
	Gastritis erosive	Gastritis erosive
	Gastroenteritis	Gastroenteritis
	Gastroenteritis viral	Gastroenteritis viral
	Gastrointestinal carcinoma	Gastrointestinal carcinoma
	Gastrointestinal disorder	Gastrointestinal disorder
	Gastrointestinal haemorrhage	Gastrointestinal haemorrhage
	Gastrointestinal pain	Gastrointestinal pain
	Gastrointestinal sounds abnormal	Gastrointestinal sounds abnormal
	Gastrointestinal ulcer	Gastrointestinal ulcer
	Gastrointestinal viral infection	Gastrointestinal viral infection
	Gastrooesophageal reflux disease	Gastrooesophageal reflux disease
	General physical health deterioration	General physical health deterioration
	Generalised oedema	Generalised oedema
	Genital discomfort	Genital discomfort
	Genital haemorrhage	Genital haemorrhage
	Genital herpes	Genital herpes
	Genital infection fungal	Genital infection fungal
	Genital rash	Genital rash
	Gingival bleeding	Gingival bleeding
○	Gingival inflammation	Noninfective gingivitis
	Gingival pain	Gingival pain
	Gingival swelling	Gingival swelling
	Gingivitis	Gingivitis
	Glaucoma	Glaucoma

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Glossitis	Glossitis
	Glossodynia	Glossodynia
	Glucose tolerance impaired	Glucose tolerance impaired
	Glucose urine	Glucose urine
	Goitre	Goitre
	Gout	Gout
	Granuloma	Granuloma
	Granuloma skin	Granuloma skin
	Groin pain	Groin pain
	Growing pains	Growing pains
	Growth of eyelashes	Growth of eyelashes
	Guillain-Barre syndrome	Guillain-Barre syndrome
	Gynaecomastia	Gynaecomastia
	Haemangioma	Haemangioma
	Haematemesis	Haematemesis
	Haematochezia	Haematochezia
	Haematocrit decreased	Haematocrit decreased
	Haematoma	Haematoma
	Haematospermia	Haematospermia
	Haematuria	Haematuria
	Haemoglobin decreased	Haemoglobin decreased
	Haemoglobin increased	Haemoglobin increased
	Haemoglobin urine	Haemoglobin urine
	Haemolytic anaemia	Haemolytic anaemia
	Haemoptysis	Haemoptysis
	Haemorrhage	Haemorrhage
	Haemorrhage intracranial	Haemorrhage intracranial
	Haemorrhage subcutaneous	Haemorrhage subcutaneous
	Haemorrhagic diathesis	Haemorrhagic diathesis
	Haemorrhagic stroke	Haemorrhagic stroke
	Haemorrhoidal haemorrhage	Haemorrhoidal haemorrhage
	Haemorrhoids	Haemorrhoids
	Haemorrhoids thrombosed	Haemorrhoids thrombosed
	Hair colour changes	Hair colour changes
	Hair disorder	Hair disorder
	Hair growth abnormal	Hair growth abnormal
	Hair texture abnormal	Hair texture abnormal
	Hallucination	Hallucination
	Hallucination, auditory	Hallucination, auditory
	Hallucination, visual	Hallucination, visual
	Hand fracture	Hand fracture
	Head discomfort	Head discomfort
	Headache	Headache
	Hearing impaired	Hearing impaired
	Heart rate increased	Heart rate increased
	Heart rate irregular	Heart rate irregular
	Helicobacter infection	Helicobacter infection
	Hemiparesis	Hemiparesis
	Hepatic enzyme increased	Hepatic enzyme increased
	Hepatic failure	Hepatic failure
	Hepatic function abnormal	Hepatic function abnormal
	Hepatic pain	Hepatic pain
	Hepatitis	Hepatitis
	Hepatocellular injury	Hepatocellular injury
	Hepatomegaly	Hepatomegaly
	Hepatorenal syndrome	Hepatorenal syndrome
	Hernia	Hernia
	Herpes virus infection	Herpes virus infection
	Herpes zoster	Herpes zoster
	Hiatus hernia	Hiatus hernia

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Hiccups	Hiccups
	Hip fracture	Hip fracture
	Hordeolum	Hordeolum
	Hot flush	Hot flush
	Humerus fracture	Humerus fracture
	Hunger	Hunger
	Hydrocephalus	Hydrocephalus
	Hydronephrosis	Hydronephrosis
	Hyperaesthesia	Hyperaesthesia
	Hyperalbuminaemia	Hyperalbuminaemia
	Hyperbilirubinaemia	Hyperbilirubinaemia
	Hypercalcaemia	Hypercalcaemia
	Hyperchlorhydria	Hyperchlorhydria
	Hypercholesterolaemia	Hypercholesterolaemia
	Hyperglycaemia	Hyperglycaemia
	Hyperhidrosis	Hyperhidrosis
	Hyperkalaemia	Hyperkalaemia
	Hyperkeratosis	Hyperkeratosis
	Hyperlipidaemia	Hyperlipidaemia
	Hypermagnesaemia	Hypermagnesaemia
	Hypermetropia	Hypermetropia
	Hypernatraemia	Hypernatraemia
	Hyperparathyroidism	Hyperparathyroidism
	Hyperphosphataemia	Hyperphosphataemia
	Hypersensitivity	Hypersensitivity
	Hypersomnia	Hypersomnia
	Hypertension	Hypertension
	Hypertensive crisis	Hypertensive crisis
	Hyperthermia	Hyperthermia
	Hyperthyroidism	Hyperthyroidism
	Hypertonic bladder	Hypertonic bladder
	Hypertrichosis	Hypertrichosis
	Hypertriglyceridaemia	Hypertriglyceridaemia
	Hyperuricaemia	Hyperuricaemia
	Hyperventilation	Hyperventilation
	Hypoacusis	Hypoacusis
	Hypoaesthesia	Hypoaesthesia
	Hypoaesthesia oral	Hypoaesthesia oral
	Hypoalbuminaemia	Hypoalbuminaemia
	Hypocalcaemia	Hypocalcaemia
	Hypogeusia	Hypogeusia
	Hypoglycaemia	Hypoglycaemia
	Hypogonadism	Hypogonadism
	Hypokalaemia	Hypokalaemia
	Hypomagnesaemia	Hypomagnesaemia
	Hyponatraemia	Hyponatraemia
	Hypoparathyroidism	Hypoparathyroidism
	Hypophagia	Hypophagia
	Hypophosphataemia	Hypophosphataemia
	Hypophysitis	Hypophysitis
	Hypopigmentation of eyelid	Hypopigmentation of eyelid
	Hypopituitarism	Hypopituitarism
	Hypotension	Hypotension
	Hypothermia	Hypothermia
	Hypothyroidism	Hypothyroidism
	Hypotonia	Hypotonia
	Hypovolaemia	Hypovolaemia
	Hypoxia	Hypoxia
	Ichthyosis acquired	Ichthyosis acquired
	Ileus	Ileus

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Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Immune thrombocytopenic purpura	Immune thrombocytopenic purpura
	Impaired gastric emptying	Impaired gastric emptying
	Impaired healing	Impaired healing
	Implant site pain	Implant site pain
	Incision site abscess	Incision site abscess
	Incision site complication	Incision site complication
	Incision site haemorrhage	Incision site haemorrhage
	Incision site pain	Incision site pain
	Incision site pruritus	Incision site pruritus
	Incision site ulcer	Incision site ulcer
	Incontinence	Incontinence
	Increased appetite	Increased appetite
	Increased bronchial secretion	Increased bronchial secretion
	Increased tendency to bruise	Increased tendency to bruise
	Increased upper airway secretion	Increased upper airway secretion
	Increased viscosity of nasal secretion	Increased viscosity of nasal secretion
	Infected dermal cyst	Infected dermal cyst
	Infected neoplasm	Infected neoplasm
	Infection	Infection
	Infectious pleural effusion	Infectious pleural effusion
	Inflammation	Inflammation
	Inflammatory pain	Inflammatory pain
	Influenza	Influenza
	Influenza like illness	Influenza like illness
	Infusion related reaction	Infusion related reaction
	Infusion site bruising	Infusion site bruising
	Infusion site extravasation	Infusion site extravasation
	Infusion site pain	Infusion site pain
	Ingrowing nail	Ingrowing nail
	Inguinal hernia	Inguinal hernia
	Inguinal mass	Inguinal mass
	Injection site extravasation	Injection site extravasation
	Injection site irritation	Injection site irritation
	Injection site pain	Injection site pain
	Injection site reaction	Injection site reaction
	Insomnia	Insomnia
	Insulin resistant diabetes	Insulin resistant diabetes
	Intermittent claudication	Intermittent claudication
	International normalised ratio increased	International normalised ratio increased
	Interstitial lung disease	Interstitial lung disease
	Intertrigo	Intertrigo
	Intervertebral disc protrusion	Intervertebral disc protrusion
	Intervertebral discitis	Intervertebral discitis
	Intestinal obstruction	Intestinal obstruction
	Intestinal perforation	Intestinal perforation
	Intra-abdominal haematoma	Intra-abdominal haematoma
	Intracranial tumour haemorrhage	Intracranial tumour haemorrhage
	Intraocular pressure test abnormal	Intraocular pressure test abnormal
	Intussusception	Intussusception
	Iridocyclitis	Iridocyclitis
	Iritis	Iritis
	Iron deficiency	Iron deficiency
	Iron deficiency anaemia	Iron deficiency anaemia
	Irritability	Irritability
	Irritable bowel syndrome	Irritable bowel syndrome
	Ischaemia	Ischaemia
	Ischaemic stroke	Ischaemic stroke
	Jaundice	Jaundice
	Joint dislocation	Joint dislocation
	Joint effusion	Joint effusion

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Joint injury	Joint injury
	Joint instability	Joint instability
	Joint range of motion decreased	Joint range of motion decreased
	Joint stiffness	Joint stiffness
	Joint swelling	Joint swelling
	Judgement impaired	Judgement impaired
	Jugular vein thrombosis	Jugular vein thrombosis
	Keratoacanthoma	Keratoacanthoma
	Keratosis pilaris	Keratosis pilaris
	Kidney infection	Kidney infection
	Klebsiella infection	Klebsiella infection
	Kyphosis	Kyphosis
	Laceration	Laceration
	Lacrimation increased	Lacrimation increased
	Lactic acidosis	Lactic acidosis
	Lacunar infarction	Lacunar infarction
	Large intestinal ulcer	Large intestinal ulcer
	Large intestine polyp	Large intestine polyp
	Laryngeal discomfort	Laryngeal discomfort
	Laryngeal inflammation	Laryngeal inflammation
	Laryngeal pain	Laryngeal pain
	Laryngitis	Laryngitis
	Left ventricular dysfunction	Left ventricular dysfunction
	Left ventricular hypertrophy	Left ventricular hypertrophy
	Lethargy	Lethargy
	Leukocytosis	Leukocytosis
	Leukopenia	Leukopenia
	Leukoplakia oral	Leukoplakia oral
	Libido decreased	Libido decreased
	Lichen planus	Lichen planus
	Lichen sclerosus	Lichen sclerosus
	Lichenification	Lichenification
	Lichenoid keratosis	Lichenoid keratosis
	Ligament sprain	Ligament sprain
	Limb discomfort	Limb discomfort
	Limb injury	Limb injury
	Linear IgA disease	Linear IgA disease
	Lip dry	Lip dry
	Lip injury	Lip injury
	Lip oedema	Lip oedema
	Lip pain	Lip pain
	Lip swelling	Lip swelling
	Lip ulceration	Lip ulceration
	Lipase	Lipase
	Lipase increased	Lipase increased
	Lipoma	Lipoma
	Liver function test abnormal	Liver function test abnormal
	Lobar pneumonia	Lobar pneumonia
	Local swelling	Local swelling
	Localised infection	Localised infection
	Localised oedema	Localised oedema
	Loose tooth	Loose tooth
	Loss of consciousness	Loss of consciousness
	Lower extremity mass	Lower extremity mass
	Lower gastrointestinal haemorrhage	Lower gastrointestinal haemorrhage
	Lower limb fracture	Lower limb fracture
	Lower respiratory tract infection	Lower respiratory tract infection
	Lumbar radiculopathy	Lumbar radiculopathy
	Lung consolidation	Lung consolidation
	Lung disorder	Lung disorder

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Lung infection	Lung infection
	Lung infiltration	Lung infiltration
	Lyme disease	Lyme disease
	Lymph gland infection	Lymph gland infection
	Lymph node pain	Lymph node pain
	Lymphadenitis	Lymphadenitis
	Lymphadenopathy	Lymphadenopathy
	Lymphangiosis carcinomatosa	Lymphangiosis carcinomatosa
	Lymphangitis	Lymphangitis
	Lymphatic fistula	Lymphatic fistula
	Lymphatic obstruction	Lymphatic obstruction
	Lymphocyte count decreased	Lymphocyte count decreased
	Lymphoedema	Lymphoedema
	Lymphopenia	Lymphopenia
	Macular degeneration	Macular degeneration
	Macule	Macule
	Madarosis	Madarosis
	Malabsorption	Malabsorption
	Malaise	Malaise
	Malignant melanoma	Malignant melanoma
	Malignant melanoma in situ	Malignant melanoma in situ
	Malnutrition	Malnutrition
	Mass	Mass
	Mastitis	Mastitis
	Medical device complication	Medical device complication
	Medical device pain	Medical device pain
	Medical observation	Medical observation
	Melaena	Melaena
	Melanocytic hyperplasia	Melanocytic hyperplasia
	Melanocytic naevus	Melanocytic naevus
	Memory impairment	Memory impairment
	Meningitis noninfective	Meningitis noninfective
	Meniscus injury	Meniscus injury
	Menopausal symptoms	Menopausal symptoms
	Menorrhagia	Menorrhagia
	Menstruation irregular	Menstruation irregular
	Mental status changes	Mental status changes
	Metabolic acidosis	Metabolic acidosis
	Metabolic disorder	Metabolic disorder
	Metastases to bone	Metastases to bone
	Metastases to central nervous system	Metastases to central nervous system
	Metastases to lymph nodes	Metastases to lymph nodes
	Metastases to meninges	Metastases to meninges
	Metastases to muscle	Metastases to muscle
	Metastatic malignant melanoma	Metastatic malignant melanoma
	Metastatic pain	Metastatic pain
	Metrorrhagia	Metrorrhagia
	Microcytic anaemia	Microcytic anaemia
	Micturition urgency	Micturition urgency
	Middle ear inflammation	Middle ear inflammation
	Middle insomnia	Middle insomnia
	Migraine	Migraine
	Migraine with aura	Migraine with aura
	Mitral valve incompetence	Mitral valve incompetence
	Mobility decreased	Mobility decreased
	Monoparesis	Monoparesis
	Mood altered	Mood altered
	Mood swings	Mood swings
	Motion sickness	Motion sickness
	Mouth haemorrhage	Mouth haemorrhage

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Mouth ulceration	Mouth ulceration
	Mucosal discolouration	Mucosal discolouration
	Mucosal dryness	Mucosal dryness
	Mucosal inflammation	Mucosal inflammation
	Mucous stools	Mucous stools
	Muscle atrophy	Muscle atrophy
	Muscle contusion	Muscle contusion
	Muscle fatigue	Muscle fatigue
	Muscle spasms	Muscle spasms
	Muscle strain	Muscle strain
	Muscle tightness	Muscle tightness
	Muscle twitching	Muscle twitching
	Muscular weakness	Muscular weakness
	Musculoskeletal chest pain	Musculoskeletal chest pain
	Musculoskeletal discomfort	Musculoskeletal discomfort
	Musculoskeletal pain	Musculoskeletal pain
	Musculoskeletal stiffness	Musculoskeletal stiffness
	Myalgia	Myalgia
	Myalgia intercostal	Myalgia intercostal
	Myasthenic syndrome	Myasthenic syndrome
	Myocardial infarction	Myocardial infarction
	Myoclonus	Myoclonus
	Myopathy	Myopathy
	Myositis	Myositis
	Naevus flammeus	Naevus flammeus
	Nail bed infection	Nail bed infection
	Nail discolouration	Nail discolouration
	Nail disorder	Nail disorder
	Nail dystrophy	Nail dystrophy
	Nail growth abnormal	Nail growth abnormal
	Nasal congestion	Nasal congestion
	Nasal discomfort	Nasal discomfort
	Nasal disorder	Nasal disorder
	Nasal dryness	Nasal dryness
	Nasal inflammation	Nasal inflammation
	Nasal mucosal disorder	Nasal mucosal disorder
	Nasal obstruction	Nasal obstruction
	Nasal ulcer	Nasal ulcer
	Nasopharyngitis	Nasopharyngitis
	Nausea	Nausea
	Neck mass	Neck mass
	Neck pain	Neck pain
	Neoplasm skin	Neoplasm skin
	Neoplasm swelling	Neoplasm swelling
	Nephrolithiasis	Nephrolithiasis
	Nerve root compression	Nerve root compression
	Nervous system disorder	Nervous system disorder
	Nervousness	Nervousness
	Neuralgia	Neuralgia
	Neurodermatitis	Neurodermatitis
	Neuropathy peripheral	Neuropathy peripheral
	Neutropenia	Neutropenia
	Neutrophil count decreased	Neutrophil count decreased
	Neutrophil count increased	Neutrophil count increased
	Neutrophilic dermatosis	Neutrophilic dermatosis
	Night sweats	Night sweats
	Nightmare	Nightmare
	Nipple pain	Nipple pain
	Nipple swelling	Nipple swelling
	Nitrite urine present	Nitrite urine present

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Nocturia	Nocturia
	Nodal osteoarthritis	Nodal osteoarthritis
	Nodule	Nodule
	Non-cardiac chest pain	Non-cardiac chest pain
	Normal pressure hydrocephalus	Normal pressure hydrocephalus
	Nuclear magnetic resonance imaging brain abnormal	Nuclear magnetic resonance imaging brain abnormal
	Obstructive uropathy	Obstructive uropathy
	Occult blood	Occult blood
	Ocular discomfort	Ocular discomfort
	Ocular hyperaemia	Ocular hyperaemia
	Odynophagia	Odynophagia
	Oedema	Oedema
	Oedema genital	Oedema genital
	Oedema peripheral	Oedema peripheral
	Oesophageal candidiasis	Oesophageal candidiasis
	Oesophageal pain	Oesophageal pain
	Oesophageal ulcer	Oesophageal ulcer
	Oesophagitis	Oesophagitis
	Oncologic complication	Oncologic complication
	Onychoclasis	Onychoclasis
	Onychomycosis	Onychomycosis
	Ophthalmic herpes zoster	Ophthalmic herpes zoster
	Ophthalmoplegia	Ophthalmoplegia
	Optic neuritis	Optic neuritis
	Optic neuropathy	Optic neuropathy
	Oral candidiasis	Oral candidiasis
	Oral disorder	Oral disorder
	Oral fungal infection	Oral fungal infection
	Oral herpes	Oral herpes
	Oral infection	Oral infection
	Oral mucosal blistering	Oral mucosal blistering
	Oral mucosal discolouration	Oral mucosal discolouration
	Oral mucosal erythema	Oral mucosal erythema
	Oral pain	Oral pain
	Oropharyngeal discomfort	Oropharyngeal discomfort
	Oropharyngeal pain	Oropharyngeal pain
	Orthopnoea	Orthopnoea
	Orthostatic hypotension	Orthostatic hypotension
	Osteitis	Osteitis
	Osteoarthritis	Osteoarthritis
	Osteolysis	Osteolysis
	Osteoporosis	Osteoporosis
	Otitis externa	Otitis externa
	Otitis media	Otitis media
	Oxygen saturation decreased	Oxygen saturation decreased
	Pain	Pain
	Pain in extremity	Pain in extremity
	Pain in jaw	Pain in jaw
	Pain of skin	Pain of skin
	Painful defaecation	Painful defaecation
	Painful respiration	Painful respiration
	Pallor	Pallor
	Palmar erythema	Palmar erythema
	Palmar-plantar erythrodysaesthesia syndrome	Palmar-plantar erythrodysaesthesia syndrome
	Palpitations	Palpitations
	Pancreatic enzymes decreased	Pancreatic enzymes decreased
	Pancreatic enzymes increased	Pancreatic enzymes increased
	Pancreatitis	Pancreatitis
	Pancytopenia	Pancytopenia

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Panic attack	Panic attack
	Panniculitis	Panniculitis
	Papillary thyroid cancer	Papillary thyroid cancer
	Papilloedema	Papilloedema
	Papilloma	Papilloma
	Papule	Papule
	Paraesthesia	Paraesthesia
	Paraesthesia oral	Paraesthesia oral
	Paralysis	Paralysis
	Paranasal sinus discomfort	Paranasal sinus discomfort
	Parapsoriasis	Parapsoriasis
	Paronychia	Paronychia
	Parosmia	Parosmia
	Partial seizures	Partial seizures
	Pathological fracture	Pathological fracture
	Pelvic abscess	Pelvic abscess
	Pelvic pain	Pelvic pain
	Pemphigoid	Pemphigoid
	Penile abscess	Penile abscess
	Penile erythema	Penile erythema
	Penile infection	Penile infection
	Penile ulceration	Penile ulceration
	Peptic ulcer	Peptic ulcer
	Performance status decreased	Performance status decreased
	Periarthritis	Periarthritis
	Pericardial effusion	Pericardial effusion
	Pericarditis	Pericarditis
	Periodontal disease	Periodontal disease
	Periorbital contusion	Periorbital contusion
	Periorbital oedema	Periorbital oedema
	Peripheral coldness	Peripheral coldness
	Peripheral embolism	Peripheral embolism
	Peripheral ischaemia	Peripheral ischaemia
	Peripheral motor neuropathy	Peripheral motor neuropathy
	Peripheral sensory neuropathy	Peripheral sensory neuropathy
	Peripheral swelling	Peripheral swelling
	Peripheral venous disease	Peripheral venous disease
	Peroneal nerve palsy	Peroneal nerve palsy
	Personality change	Personality change
	Petechiae	Petechiae
	Phantom pain	Phantom pain
	Pharyngeal oedema	Pharyngeal oedema
	Pharyngitis	Pharyngitis
	Phlebitis	Phlebitis
	Phobia	Phobia
	Photophobia	Photophobia
	Photopsia	Photopsia
	Photosensitivity reaction	Photosensitivity reaction
	Pigmentation disorder	Pigmentation disorder
	Plantar fasciitis	Plantar fasciitis
	Platelet count decreased	Platelet count decreased
	Platelet count increased	Platelet count increased
	Pleural effusion	Pleural effusion
	Pleurisy	Pleurisy
	Pleuritic pain	Pleuritic pain
	Pneumaturia	Pneumaturia
	Pneumonia	Pneumonia
	Pneumonia aspiration	Pneumonia aspiration
	Pneumonia klebsiella	Pneumonia klebsiella
	Pneumonitis	Pneumonitis

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Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Pneumothorax	Pneumothorax
	Pollakiuria	Pollakiuria
	Polyarthritis	Polyarthritis
	Polycythaemia	Polycythaemia
	Polymyalgia rheumatica	Polymyalgia rheumatica
	Polyneuropathy	Polyneuropathy
	Poor quality sleep	Poor quality sleep
	Poor venous access	Poor venous access
	Post herpetic neuralgia	Post herpetic neuralgia
	Post procedural cellulitis	Post procedural cellulitis
	Post procedural complication	Post procedural complication
	Post procedural discomfort	Post procedural discomfort
	Post procedural haematoma	Post procedural haematoma
	Post procedural haemorrhage	Post procedural haemorrhage
	Post procedural hypothyroidism	Post procedural hypothyroidism
	Post procedural infection	Post procedural infection
	Post-traumatic pain	Post-traumatic pain
	Post-tussive vomiting	Post-tussive vomiting
	Postoperative wound infection	Postoperative wound infection
	Postrenal failure	Postrenal failure
	Presyncope	Presyncope
	Primary hypothyroidism	Primary hypothyroidism
	Procedural pain	Procedural pain
	Proctalgia	Proctalgia
	Proctitis	Proctitis
	Productive cough	Productive cough
	Prostatitis	Prostatitis
	Proteinuria	Proteinuria
	Prurigo	Prurigo
	Pruritus	Pruritus
	Pruritus allergic	Pruritus allergic
	Pruritus generalised	Pruritus generalised
	Pruritus genital	Pruritus genital
	Pseudofolliculitis barbae	Pseudofolliculitis barbae
	Pseudomonas infection	Pseudomonas infection
	Psoriasis	Psoriasis
	Psychosomatic disease	Psychosomatic disease
	Psychotic disorder	Psychotic disorder
	Pulmonary congestion	Pulmonary congestion
	Pulmonary embolism	Pulmonary embolism
	Pulmonary haemorrhage	Pulmonary haemorrhage
	Pulmonary hypertension	Pulmonary hypertension
	Pulmonary infarction	Pulmonary infarction
	Pulmonary oedema	Pulmonary oedema
	Pulmonary thrombosis	Pulmonary thrombosis
	Pulpitis dental	Pulpitis dental
	Puncture site erythema	Puncture site erythema
	Pupils unequal	Pupils unequal
	Purpura	Purpura
	Pustular psoriasis	Pustular psoriasis
	Pyelonephritis	Pyelonephritis
	Pyrexia	Pyrexia
	Radiation injury	Radiation injury
	Radiation necrosis	Radiation necrosis
	Radiation proctitis	Radiation proctitis
	Radiation skin injury	Radiation skin injury
	Radiculopathy	Radiculopathy
	Rales	Rales
	Rash	Rash
	Rash erythematous	Rash erythematous

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Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Rash follicular	Rash follicular
	Rash generalised	Rash generalised
	Rash macular	Rash macular
	Rash maculo-papular	Rash maculo-papular
	Rash papular	Rash papular
	Rash pruritic	Rash pruritic
	Rash pustular	Rash pustular
	Rash vesicular	Rash vesicular
	Raynaud's phenomenon	Raynaud's phenomenon
	Rectal haemorrhage	Rectal haemorrhage
	Rectal tenesmus	Rectal tenesmus
	Reflux gastritis	Reflux gastritis
	Regurgitation	Regurgitation
	Renal colic	Renal colic
	Renal cyst	Renal cyst
	Renal failure	Renal failure
○	Renal failure acute	Acute kidney injury
○	Renal failure chronic	Chronic kidney disease
	Renal impairment	Renal impairment
	Renal infarct	Renal infarct
	Renal pain	Renal pain
	Respiratory disorder	Respiratory disorder
	Respiratory distress	Respiratory distress
	Respiratory failure	Respiratory failure
	Respiratory tract congestion	Respiratory tract congestion
	Respiratory tract haemorrhage	Respiratory tract haemorrhage
	Respiratory tract infection	Respiratory tract infection
	Respiratory tract infection viral	Respiratory tract infection viral
	Restless legs syndrome	Restless legs syndrome
	Restlessness	Restlessness
	Retching	Retching
	Retinal detachment	Retinal detachment
	Retinal haemorrhage	Retinal haemorrhage
	Retinal pigment epitheliopathy	Retinal pigment epitheliopathy
	Retinal tear	Retinal tear
	Retinal vein occlusion	Retinal vein occlusion
	Retroperitoneal haemorrhage	Retroperitoneal haemorrhage
	Rhabdomyolysis	Rhabdomyolysis
	Rheumatic disorder	Rheumatic disorder
	Rheumatoid arthritis	Rheumatoid arthritis
	Rhinitis	Rhinitis
	Rhinitis allergic	Rhinitis allergic
	Rhinorrhoea	Rhinorrhoea
	Rib fracture	Rib fracture
	Rosacea	Rosacea
	Rotator cuff syndrome	Rotator cuff syndrome
	Saliva altered	Saliva altered
	Salivary gland disorder	Salivary gland disorder
	Salmonellosis	Salmonellosis
	Sarcoidosis	Sarcoidosis
	Scab	Scab
	Scar pain	Scar pain
	Sciatica	Sciatica
	Scleral hyperaemia	Scleral hyperaemia
	Scleritis	Scleritis
	Scratch	Scratch
	Scrotal erythema	Scrotal erythema
	Scrotal oedema	Scrotal oedema
	Scrotal pain	Scrotal pain
	Seasonal allergy	Seasonal allergy

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Sebaceous gland disorder	Sebaceous gland disorder
	Seborrhoea	Seborrhoea
	Seborrhoeic dermatitis	Seborrhoeic dermatitis
	Seborrhoeic keratosis	Seborrhoeic keratosis
	Secretion discharge	Secretion discharge
	Sensation of foreign body	Sensation of foreign body
	Sensitivity of teeth	Sensitivity of teeth
	Sensory disturbance	Sensory disturbance
	Sensory loss	Sensory loss
	Sepsis	Sepsis
	Septic shock	Septic shock
	Seroma	Seroma
	Sexual dysfunction	Sexual dysfunction
	Sinus bradycardia	Sinus bradycardia
	Sinus congestion	Sinus congestion
	Sinus headache	Sinus headache
	Sinus tachycardia	Sinus tachycardia
	Sinusitis	Sinusitis
	Sinusitis bacterial	Sinusitis bacterial
	Sjogren's syndrome	Sjogren's syndrome
	Skeletal injury	Skeletal injury
	Skin abrasion	Skin abrasion
	Skin burning sensation	Skin burning sensation
	Skin candida	Skin candida
	Skin depigmentation	Skin depigmentation
	Skin discolouration	Skin discolouration
	Skin disorder	Skin disorder
	Skin exfoliation	Skin exfoliation
	Skin fissures	Skin fissures
	Skin haemorrhage	Skin haemorrhage
	Skin hyperpigmentation	Skin hyperpigmentation
	Skin hypopigmentation	Skin hypopigmentation
	Skin infection	Skin infection
	Skin irritation	Skin irritation
	Skin lesion	Skin lesion
	Skin maceration	Skin maceration
	Skin mass	Skin mass
	Skin neoplasm bleeding	Skin neoplasm bleeding
	Skin neoplasm excision	Skin neoplasm excision
	Skin papilloma	Skin papilloma
	Skin plaque	Skin plaque
	Skin striae	Skin striae
	Skin ulcer	Skin ulcer
	Skin wound	Skin wound
	Sleep apnoea syndrome	Sleep apnoea syndrome
	Sleep disorder	Sleep disorder
	Small intestinal obstruction	Small intestinal obstruction
	Small intestinal perforation	Small intestinal perforation
	Sneezing	Sneezing
	Soft tissue infection	Soft tissue infection
	Solar dermatitis	Solar dermatitis
	Somnolence	Somnolence
	Spinal column stenosis	Spinal column stenosis
	Spinal compression fracture	Spinal compression fracture
	Spinal cord compression	Spinal cord compression
	Spinal fracture	Spinal fracture
	Spinal osteoarthritis	Spinal osteoarthritis
	Spinal pain	Spinal pain
	Splenic artery aneurysm	Splenic artery aneurysm
	Splenic infarction	Splenic infarction

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Spondylolisthesis	Spondylolisthesis
	Squamous cell carcinoma	Squamous cell carcinoma
	Squamous cell carcinoma of skin	Squamous cell carcinoma of skin
	Staphylococcal infection	Staphylococcal infection
	Staphylococcal skin infection	Staphylococcal skin infection
	Stasis dermatitis	Stasis dermatitis
	Sternal fracture	Sternal fracture
	Stevens-Johnson syndrome	Stevens-Johnson syndrome
	Stomatitis	Stomatitis
	Stomatitis necrotising	Stomatitis necrotising
	Stress	Stress
	Stress fracture	Stress fracture
	Subclavian vein thrombosis	Subclavian vein thrombosis
	Subcutaneous abscess	Subcutaneous abscess
	Subdural haematoma	Subdural haematoma
	Subileus	Subileus
	Suicidal ideation	Suicidal ideation
	Sunburn	Sunburn
	Superior vena cava occlusion	Superior vena cava occlusion
	Superior vena cava syndrome	Superior vena cava syndrome
	Supraventricular tachycardia	Supraventricular tachycardia
	Swelling	Swelling
	Swelling face	Swelling face
	Syncope	Syncope
	Synovial cyst	Synovial cyst
	Synovial rupture	Synovial rupture
	Synovitis	Synovitis
	Systemic inflammatory response syndrome	Systemic inflammatory response syndrome
	Tachycardia	Tachycardia
	Tachypnoea	Tachypnoea
	Temperature intolerance	Temperature intolerance
	Temporomandibular joint syndrome	Temporomandibular joint syndrome
	Tendon disorder	Tendon disorder
	Tendon pain	Tendon pain
	Tendon rupture	Tendon rupture
	Tendonitis	Tendonitis
	Tenosynovitis	Tenosynovitis
	Tension	Tension
	Tension headache	Tension headache
	Testicular atrophy	Testicular atrophy
	Testicular pain	Testicular pain
	Thermal burn	Thermal burn
	Thirst	Thirst
	Throat irritation	Throat irritation
	Thrombocytopenia	Thrombocytopenia
	Thrombocytosis	Thrombocytosis
	Thrombophlebitis superficial	Thrombophlebitis superficial
	Thyroglobulin increased	Thyroglobulin increased
	Thyroid neoplasm	Thyroid neoplasm
	Thyroiditis	Thyroiditis
	Thyroxine decreased	Thyroxine decreased
	Thyroxine free increased	Thyroxine free increased
	Thyroxine increased	Thyroxine increased
	Tinea cruris	Tinea cruris
	Tinea infection	Tinea infection
	Tinea pedis	Tinea pedis
	Tinea versicolour	Tinea versicolour
	Tinnitus	Tinnitus
	Tongue coated	Tongue coated
	Tongue discolouration	Tongue discolouration

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Tongue haemorrhage	Tongue haemorrhage
	Tongue ulceration	Tongue ulceration
	Tonsillar disorder	Tonsillar disorder
	Tooth abscess	Tooth abscess
	Tooth demineralisation	Tooth demineralisation
	Tooth disorder	Tooth disorder
	Tooth fracture	Tooth fracture
	Tooth infection	Tooth infection
	Tooth loss	Tooth loss
	Toothache	Toothache
	Torticollis	Torticollis
	Tracheitis	Tracheitis
	Trance	Trance
	Transaminases increased	Transaminases increased
	Transfusion reaction	Transfusion reaction
	Transient acantholytic dermatosis	Transient acantholytic dermatosis
	Transient ischaemic attack	Transient ischaemic attack
	Tremor	Tremor
	Tri-iodothyronine decreased	Tri-iodothyronine decreased
	Tri-iodothyronine free decreased	Tri-iodothyronine free decreased
	Tri-iodothyronine increased	Tri-iodothyronine increased
	Trigeminal neuralgia	Trigeminal neuralgia
	Trigger finger	Trigger finger
	Trismus	Trismus
	Troponin increased	Troponin increased
	Tuberculosis	Tuberculosis
	Tubulointerstitial nephritis	Tubulointerstitial nephritis
	Tumour haemorrhage	Tumour haemorrhage
	Tumour lysis syndrome	Tumour lysis syndrome
	Tumour necrosis	Tumour necrosis
	Tumour pain	Tumour pain
	Type 1 diabetes mellitus	Type 1 diabetes mellitus
	Umbilical hernia, obstructive	Umbilical hernia, obstructive
	Upper extremity mass	Upper extremity mass
	Upper gastrointestinal haemorrhage	Upper gastrointestinal haemorrhage
	Upper respiratory tract infection	Upper respiratory tract infection
	Upper-airway cough syndrome	Upper-airway cough syndrome
	Urinary hesitation	Urinary hesitation
	Urinary incontinence	Urinary incontinence
	Urinary retention	Urinary retention
	Urinary retention postoperative	Urinary retention postoperative
	Urinary tract disorder	Urinary tract disorder
	Urinary tract infection	Urinary tract infection
	Urinary tract infection viral	Urinary tract infection viral
	Urinary tract pain	Urinary tract pain
	Urine flow decreased	Urine flow decreased
	Urine leukocyte esterase positive	Urine leukocyte esterase positive
	Urine odour abnormal	Urine odour abnormal
	Urine output decreased	Urine output decreased
	Urticaria	Urticaria
	Urticaria papular	Urticaria papular
	Uveitis	Uveitis
	VIIth nerve paralysis	VIIth nerve paralysis
	Vaginal discharge	Vaginal discharge
	Vaginal haemorrhage	Vaginal haemorrhage
	Vaginal infection	Vaginal infection
	Varicophlebitis	Varicophlebitis
	Vasculitis	Vasculitis
	Vasogenic cerebral oedema	Vasogenic cerebral oedema
	Vein disorder	Vein disorder

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付録 2.7.4-16 併合解析で用いた MedDRA version 17.1 と MedDRA version 18.0 の比較（続き）

Ver.18.0で変更あり	MedDRA version 17.1	MedDRA version 18.0
	Vena cava thrombosis	Vena cava thrombosis
	Venous thrombosis	Venous thrombosis
	Ventricular extrasystoles	Ventricular extrasystoles
	Vertigo	Vertigo
	Vertigo positional	Vertigo positional
	Vessel puncture site pain	Vessel puncture site pain
	Viral infection	Viral infection
	Viral pharyngitis	Viral pharyngitis
	Viral rhinitis	Viral rhinitis
	Viral sinusitis	Viral sinusitis
	Viral upper respiratory tract infection	Viral upper respiratory tract infection
	Vision blurred	Vision blurred
	Visual acuity reduced	Visual acuity reduced
	Visual field defect	Visual field defect
	Visual impairment	Visual impairment
	Vitamin B12 deficiency	Vitamin B12 deficiency
	Vitamin D decreased	Vitamin D decreased
	Vitamin D deficiency	Vitamin D deficiency
	Vitiligo	Vitiligo
	Vitreous detachment	Vitreous detachment
	Vitreous floaters	Vitreous floaters
	Vomiting	Vomiting
	Vulval cancer metastatic	Vulval cancer metastatic
	Vulval disorder	Vulval disorder
	Vulvovaginal candidiasis	Vulvovaginal candidiasis
	Vulvovaginal discomfort	Vulvovaginal discomfort
	Vulvovaginal dryness	Vulvovaginal dryness
	Vulvovaginal mycotic infection	Vulvovaginal mycotic infection
	Vulvovaginal pain	Vulvovaginal pain
	Vulvovaginal pruritus	Vulvovaginal pruritus
	Weight decreased	Weight decreased
	Weight increased	Weight increased
	Wheezing	Wheezing
	White blood cell count decreased	White blood cell count decreased
	White blood cell count increased	White blood cell count increased
	Wound	Wound
	Wound complication	Wound complication
	Wound decomposition	Wound decomposition
	Wound haemorrhage	Wound haemorrhage
	Wound infection	Wound infection
	Wound necrosis	Wound necrosis
	Wound secretion	Wound secretion
	Wrist fracture	Wrist fracture
	Xanthelasma	Xanthelasma
	Xeroderma	Xeroderma
	Xerosis	Xerosis
	Yersinia infection	Yersinia infection

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付録 2.7.4-17 副作用（発現割合 0%超）
041 試験（APaT 集団）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Subjects in population	42			
with one or more adverse events	34	(81.0)	8	(19.0)
with no adverse events	8	(19.0)	34	(81.0)
Blood and lymphatic system disorders	**2**	**(4.8)**	**2**	**(4.8)**
Anaemia	2	(4.8)	2	(4.8)
Lymphopenia	1	(2.4)	1	(2.4)
Ear and labyrinth disorders	**1**	**(2.4)**	**0**	**(0.0)**
Vertigo	1	(2.4)	0	(0.0)
Endocrine disorders	**8**	**(19.0)**	**1**	**(2.4)**
Hyperthyroidism	2	(4.8)	0	(0.0)
Hypophysitis	2	(4.8)	1	(2.4)
Hypothyroidism	4	(9.5)	0	(0.0)
Eye disorders	**1**	**(2.4)**	**0**	**(0.0)**
Uveitis	1	(2.4)	0	(0.0)
Gastrointestinal disorders	**7**	**(16.7)**	**1**	**(2.4)**
Abdominal pain	2	(4.8)	0	(0.0)
Abdominal pain upper	2	(4.8)	0	(0.0)
Colitis	2	(4.8)	1	(2.4)
Diarrhoea	3	(7.1)	0	(0.0)
Nausea	2	(4.8)	0	(0.0)
General disorders and administration site conditions	**9**	**(21.4)**	**1**	**(2.4)**
Chest discomfort	1	(2.4)	0	(0.0)
Death	1	(2.4)	1	(2.4)
Fatigue	1	(2.4)	0	(0.0)
Malaise	5	(11.9)	0	(0.0)
Oedema peripheral	1	(2.4)	0	(0.0)
Thirst	1	(2.4)	0	(0.0)
Hepatobiliary disorders	**1**	**(2.4)**	**1**	**(2.4)**
Bile duct obstruction	1	(2.4)	1	(2.4)
Immune system disorders	**1**	**(2.4)**	**0**	**(0.0)**
Cytokine release syndrome	1	(2.4)	0	(0.0)

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付録 2.7.4-17 副作用（発現割合 0%超）

041 試験（APaT 集団）（続き）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Infections and infestations	**2**	**(4.8)**	**0**	**(0.0)**
Gastroenteritis	1	(2.4)	0	(0.0)
Lung infection	1	(2.4)	0	(0.0)
Investigations	**12**	**(28.6)**	**0**	**(0.0)**
Alanine aminotransferase increased	2	(4.8)	0	(0.0)
Aspartate aminotransferase increased	3	(7.1)	0	(0.0)
Blood creatine phosphokinase increased	1	(2.4)	0	(0.0)
Blood thyroid stimulating hormone decreased	1	(2.4)	0	(0.0)
Blood thyroid stimulating hormone increased	1	(2.4)	0	(0.0)
Blood urine	1	(2.4)	0	(0.0)
Eosinophil count increased	3	(7.1)	0	(0.0)
Thyroid function test abnormal	1	(2.4)	0	(0.0)
Weight decreased	1	(2.4)	0	(0.0)
Weight increased	1	(2.4)	0	(0.0)
Metabolism and nutrition disorders	**4**	**(9.5)**	**1**	**(2.4)**
Decreased appetite	1	(2.4)	0	(0.0)
Hyperglycaemia	1	(2.4)	1	(2.4)
Hyperkalaemia	1	(2.4)	0	(0.0)
Hyperuricaemia	1	(2.4)	0	(0.0)
Musculoskeletal and connective tissue disorders	**1**	**(2.4)**	**0**	**(0.0)**
Arthritis	1	(2.4)	0	(0.0)
Nervous system disorders	**2**	**(4.8)**	**1**	**(2.4)**
Cerebral haemorrhage	1	(2.4)	1	(2.4)
Dysgeusia	1	(2.4)	0	(0.0)
Encephalopathy	1	(2.4)	1	(2.4)
Reproductive system and breast disorders	**1**	**(2.4)**	**0**	**(0.0)**
Prostatic obstruction	1	(2.4)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**5**	**(11.9)**	**0**	**(0.0)**
Cough	1	(2.4)	0	(0.0)

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付録 2.7.4-17 副作用（発現割合 0%超）
041 試験（APaT 集団）（続き）

	Subjects With Advanced Melanoma			
	All Grades		Grades 3 – 5	
	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**5**	**(11.9)**	**0**	**(0.0)**
Dyspnoea	1	(2.4)	0	(0.0)
Epistaxis	1	(2.4)	0	(0.0)
Oropharyngeal pain	1	(2.4)	0	(0.0)
Pneumonitis	1	(2.4)	0	(0.0)
Skin and subcutaneous tissue disorders	**19**	**(45.2)**	**1**	**(2.4)**
Alopecia	1	(2.4)	0	(0.0)
Drug eruption	1	(2.4)	1	(2.4)
Dry skin	2	(4.8)	0	(0.0)
Eczema	1	(2.4)	0	(0.0)
Papule	1	(2.4)	0	(0.0)
Pruritus	6	(14.3)	0	(0.0)
Rash	1	(2.4)	0	(0.0)
Rash maculo-papular	6	(14.3)	0	(0.0)
Skin hypopigmentation	2	(4.8)	0	(0.0)
Toxic skin eruption	1	(2.4)	0	(0.0)
Urticaria	1	(2.4)	0	(0.0)
Vitiligo	3	(7.1)	0	(0.0)
Vascular disorders	**1**	**(2.4)**	**0**	**(0.0)**
Hypertension	1	(2.4)	0	(0.0)

Every subject is counted a single time for each applicable row and column.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.

Grades are based on NCI CTCAE version 4.0.

MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.

Adverse event terms are from MedDRA Version 18.0.

(Database Cutoff Date: [redacted].

Data Source: [資料5.3.5.2.3: P041V01]

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Subjects in population	382				769				458				1,609			
with one or more adverse events	289	(75.7)	58	(15.2)	595	(77.4)	81	(10.5)	371	(81.0)	71	(15.5)	1,255	(78.0)	210	(13.1)
with no adverse events	93	(24.3)	324	(84.8)	174	(22.6)	688	(89.5)	87	(19.0)	387	(84.5)	354	(22.0)	1,399	(86.9)
Blood and lymphatic system disorders	**24**	**(6.3)**	**7**	**(1.8)**	**37**	**(4.8)**	**2**	**(0.3)**	**23**	**(5.0)**	**7**	**(1.5)**	**84**	**(5.2)**	**16**	**(1.0)**
Anaemia	16	(4.2)	6	(1.6)	19	(2.5)	0	(0.0)	12	(2.6)	3	(0.7)	47	(2.9)	9	(0.6)
Eosinophilia	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	2	(0.4)	0	(0.0)	10	(0.6)	0	(0.0)
Haemolytic anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Immune thrombocytopenic purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Iron deficiency anaemia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Leukocytosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Leukopenia	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Lymph node pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphadenitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Lymphopenia	2	(0.5)	1	(0.3)	4	(0.5)	0	(0.0)	2	(0.4)	1	(0.2)	8	(0.5)	2	(0.1)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Blood and lymphatic system disorders	**24**	**(6.3)**	**7**	**(1.8)**	**37**	**(4.8)**	**2**	**(0.3)**	**23**	**(5.0)**	**7**	**(1.5)**	**84**	**(5.2)**	**16**	**(1.0)**
Neutropenia	2	(0.5)	1	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	1	(0.1)
Pancytopenia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Thrombocytopenia	4	(1.0)	0	(0.0)	6	(0.8)	2	(0.3)	4	(0.9)	0	(0.0)	14	(0.9)	2	(0.1)
Cardiac disorders	**3**	**(0.8)**	**2**	**(0.5)**	**2**	**(0.3)**	**0**	**(0.0)**	**5**	**(1.1)**	**1**	**(0.2)**	**10**	**(0.6)**	**3**	**(0.2)**
Atrial fibrillation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	2	(0.1)	1	(0.1)
Cyanosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Palpitations	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Pericardial effusion	2	(0.5)	2	(0.5)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	2	(0.1)
Pericarditis	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Tachycardia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Ear and labyrinth disorders	**4**	**(1.0)**	**0**	**(0.0)**	**8**	**(1.0)**	**0**	**(0.0)**	**2**	**(0.4)**	**0**	**(0.0)**	**14**	**(0.9)**	**0**	**(0.0)**
External ear pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Hearing impaired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Vertigo	3	(0.8)	0	(0.0)	8	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	11	(0.7)	0	(0.0)
Vertigo positional	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Endocrine disorders	**42**	**(11.0)**	**3**	**(0.8)**	**69**	**(9.0)**	**6**	**(0.8)**	**55**	**(12.0)**	**6**	**(1.3)**	**166**	**(10.3)**	**15**	**(0.9)**

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Endocrine disorders	**42**	**(11.0)**	**3**	**(0.8)**	**69**	**(9.0)**	**6**	**(0.8)**	**55**	**(12.0)**	**6**	**(1.3)**	**166**	**(10.3)**	**15**	**(0.9)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	4	(0.5)	2	(0.3)	3	(0.7)	2	(0.4)	7	(0.4)	4	(0.2)
Autoimmune thyroiditis	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Endocrine disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperparathyroidism	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperthyroidism	11	(2.9)	0	(0.0)	15	(2.0)	1	(0.1)	21	(4.6)	1	(0.2)	47	(2.9)	2	(0.1)
Hypophysitis	5	(1.3)	3	(0.8)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	7	(0.4)	4	(0.2)
Hypopituitarism	1	(0.3)	0	(0.0)	2	(0.3)	2	(0.3)	2	(0.4)	1	(0.2)	5	(0.3)	3	(0.2)
Hypothyroidism	27	(7.1)	0	(0.0)	49	(6.4)	0	(0.0)	42	(9.2)	2	(0.4)	118	(7.3)	2	(0.1)
Primary hypothyroidism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroiditis	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Eye disorders	**21**	**(5.5)**	**0**	**(0.0)**	**39**	**(5.1)**	**2**	**(0.3)**	**27**	**(5.9)**	**0**	**(0.0)**	**87**	**(5.4)**	**2**	**(0.1)**
Abnormal sensation in eye	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Asthenopia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Conjunctival hyperaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Diplopia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**21**	**(5.5)**	**0**	**(0.0)**	**39**	**(5.1)**	**2**	**(0.3)**	**27**	**(5.9)**	**0**	**(0.0)**	**87**	**(5.4)**	**2**	**(0.1)**
Dry eye	4	(1.0)	0	(0.0)	6	(0.8)	0	(0.0)	7	(1.5)	0	(0.0)	17	(1.1)	0	(0.0)
Eczema eyelids	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eye disorder	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Eye irritation	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Eye pain	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Eye pruritus	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Eye swelling	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Eyelash discolouration	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Eyelid disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelid exfoliation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eyelid oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Foreign body sensation in eyes	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Growth of eyelashes	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypopigmentation of eyelid	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Iridocyclitis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Iritis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)
Lacrimation increased	3	(0.8)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye disorders	**21**	**(5.5)**	**0**	**(0.0)**	**39**	**(5.1)**	**2**	**(0.3)**	**27**	**(5.9)**	**0**	**(0.0)**	**87**	**(5.4)**	**2**	**(0.1)**
Macular degeneration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ocular discomfort	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Ocular hyperaemia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Papilloedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Periorbital oedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Photophobia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Photopsia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Scleritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Uveitis	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	1	(0.2)	0	(0.0)	9	(0.6)	0	(0.0)
Vision blurred	3	(0.8)	0	(0.0)	6	(0.8)	0	(0.0)	2	(0.4)	0	(0.0)	11	(0.7)	0	(0.0)
Visual impairment	5	(1.3)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	0	(0.0)	11	(0.7)	0	(0.0)
Vitreous floaters	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Gastrointestinal disorders	**95**	**(24.9)**	**11**	**(2.9)**	**232**	**(30.2)**	**22**	**(2.9)**	**165**	**(36.0)**	**19**	**(4.1)**	**492**	**(30.6)**	**52**	**(3.2)**
Abdominal discomfort	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	3	(0.7)	0	(0.0)	11	(0.7)	0	(0.0)
Abdominal distension	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	5	(1.1)	0	(0.0)	13	(0.8)	0	(0.0)
Abdominal pain	14	(3.7)	0	(0.0)	16	(2.1)	1	(0.1)	21	(4.6)	0	(0.0)	51	(3.2)	1	(0.1)
Abdominal pain lower	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**95**	**(24.9)**	**11**	**(2.9)**	**232**	**(30.2)**	**22**	**(2.9)**	**165**	**(36.0)**	**19**	**(4.1)**	**492**	**(30.6)**	**52**	**(3.2)**
Abdominal pain upper	4	(1.0)	0	(0.0)	13	(1.7)	0	(0.0)	7	(1.5)	0	(0.0)	24	(1.5)	0	(0.0)
Aerophagia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aphthous stomatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aptyalism	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ascites	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Autoimmune pancreatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Chapped lips	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cheilitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Colitis	5	(1.3)	3	(0.8)	14	(1.8)	9	(1.2)	6	(1.3)	5	(1.1)	25	(1.6)	17	(1.1)
Colitis microscopic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Constipation	13	(3.4)	0	(0.0)	23	(3.0)	0	(0.0)	16	(3.5)	0	(0.0)	52	(3.2)	0	(0.0)
Defaecation urgency	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Diarrhoea	43	(11.3)	1	(0.3)	107	(13.9)	7	(0.9)	89	(19.4)	10	(2.2)	239	(14.9)	18	(1.1)
Dry mouth	5	(1.3)	0	(0.0)	19	(2.5)	0	(0.0)	29	(6.3)	0	(0.0)	53	(3.3)	0	(0.0)
Duodenitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dyspepsia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	5	(1.1)	0	(0.0)	7	(0.4)	0	(0.0)
Dysphagia	3	(0.8)	1	(0.3)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	1	(0.1)
Enteritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Enterocolitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**95**	**(24.9)**	**11**	**(2.9)**	**232**	**(30.2)**	**22**	**(2.9)**	**165**	**(36.0)**	**19**	**(4.1)**	**492**	**(30.6)**	**52**	**(3.2)**
Epigastric discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Faeces hard	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Faeces soft	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Flatulence	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Food poisoning	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Frequent bowel movements	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Gastritis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Gastrointestinal sounds abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastrooesophageal reflux disease	3	(0.8)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Gingival bleeding	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gingival pain	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Glossitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haemorrhoids	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Ileus	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Intestinal obstruction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**95**	**(24.9)**	**11**	**(2.9)**	**232**	**(30.2)**	**22**	**(2.9)**	**165**	**(36.0)**	**19**	**(4.1)**	**492**	**(30.6)**	**52**	**(3.2)**
Intussusception	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Irritable bowel syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Lip oedema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Mouth ulceration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Mucous stools	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nausea	28	(7.3)	1	(0.3)	94	(12.2)	2	(0.3)	60	(13.1)	1	(0.2)	182	(11.3)	4	(0.2)
Odynophagia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oesophagitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Oral mucosal blistering	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oral pain	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Pancreatitis	1	(0.3)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	3	(0.2)	1	(0.1)
Periodontal disease	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rectal haemorrhage	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Regurgitation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Retching	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Salivary gland disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sensitivity of teeth	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Small intestinal perforation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**95**	**(24.9)**	**11**	**(2.9)**	**232**	**(30.2)**	**22**	**(2.9)**	**165**	**(36.0)**	**19**	**(4.1)**	**492**	**(30.6)**	**52**	**(3.2)**
Stomatitis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Tongue discolouration	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tooth demineralisation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tooth disorder	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Upper gastrointestinal haemorrhage	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Vomiting	11	(2.9)	3	(0.8)	29	(3.8)	1	(0.1)	20	(4.4)	2	(0.4)	60	(3.7)	6	(0.4)
General disorders and administration site conditions	**144**	**(37.7)**	**15**	**(3.9)**	**322**	**(41.9)**	**9**	**(1.2)**	**222**	**(48.5)**	**7**	**(1.5)**	**688**	**(42.8)**	**31**	**(1.9)**
Adverse drug reaction	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Asthenia	17	(4.5)	3	(0.8)	69	(9.0)	2	(0.3)	54	(11.8)	2	(0.4)	140	(8.7)	7	(0.4)
Axillary pain	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Chest discomfort	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Chest pain	2	(0.5)	1	(0.3)	5	(0.7)	0	(0.0)	3	(0.7)	0	(0.0)	10	(0.6)	1	(0.1)
Chills	16	(4.2)	0	(0.0)	24	(3.1)	0	(0.0)	15	(3.3)	0	(0.0)	55	(3.4)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**144**	**(37.7)**	**15**	**(3.9)**	**322**	**(41.9)**	**9**	**(1.2)**	**222**	**(48.5)**	**7**	**(1.5)**	**688**	**(42.8)**	**31**	**(1.9)**
Death	2	(0.5)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Face oedema	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Facial pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Fatigue	91	(23.8)	8	(2.1)	215	(28.0)	4	(0.5)	143	(31.2)	4	(0.9)	449	(27.9)	16	(1.0)
Feeling cold	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Feeling hot	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Gait disturbance	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
General physical health deterioration	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Generalised oedema	2	(0.5)	2	(0.5)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	2	(0.1)
Hyperthermia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Hypothermia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Inflammation	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Inflammatory pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Influenza like illness	4	(1.0)	0	(0.0)	19	(2.5)	0	(0.0)	7	(1.5)	0	(0.0)	30	(1.9)	0	(0.0)
Injection site extravasation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**144**	**(37.7)**	**15**	**(3.9)**	**322**	**(41.9)**	**9**	**(1.2)**	**222**	**(48.5)**	**7**	**(1.5)**	**688**	**(42.8)**	**31**	**(1.9)**
Injection site reaction	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Localised oedema	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Malaise	9	(2.4)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	13	(0.8)	0	(0.0)
Mucosal discolouration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Mucosal inflammation	4	(1.0)	0	(0.0)	7	(0.9)	1	(0.1)	3	(0.7)	0	(0.0)	14	(0.9)	1	(0.1)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oedema	2	(0.5)	0	(0.0)	5	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Oedema peripheral	11	(2.9)	0	(0.0)	11	(1.4)	0	(0.0)	12	(2.6)	0	(0.0)	34	(2.1)	0	(0.0)
Pain	4	(1.0)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	1	(0.2)	9	(0.6)	1	(0.1)
Performance status decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Pyrexia	10	(2.6)	0	(0.0)	36	(4.7)	1	(0.1)	27	(5.9)	0	(0.0)	73	(4.5)	1	(0.1)
Swelling	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**144**	**(37.7)**	**15**	**(3.9)**	**322**	**(41.9)**	**9**	**(1.2)**	**222**	**(48.5)**	**7**	**(1.5)**	**688**	**(42.8)**	**31**	**(1.9)**
Systemic inflammatory response syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Temperature intolerance	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Thirst	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Xerosis	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Hepatobiliary disorders	**7**	**(1.8)**	**4**	**(1.0)**	**9**	**(1.2)**	**6**	**(0.8)**	**4**	**(0.9)**	**4**	**(0.9)**	**20**	**(1.2)**	**14**	**(0.9)**
Autoimmune hepatitis	4	(1.0)	3	(0.8)	3	(0.4)	2	(0.3)	2	(0.4)	2	(0.4)	9	(0.6)	7	(0.4)
Bile duct obstruction	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Cholestasis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Drug-induced liver injury	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Hepatitis	1	(0.3)	0	(0.0)	3	(0.4)	3	(0.4)	1	(0.2)	1	(0.2)	5	(0.3)	4	(0.2)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Hepatobiliary disorders	**7**	**(1.8)**	**4**	**(1.0)**	**9**	**(1.2)**	**6**	**(0.8)**	**4**	**(0.9)**	**4**	**(0.9)**	**20**	**(1.2)**	**14**	**(0.9)**
Hyperbilirubinaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Immune system disorders	**4**	**(1.0)**	**0**	**(0.0)**	**10**	**(1.3)**	**2**	**(0.3)**	**5**	**(1.1)**	**1**	**(0.2)**	**19**	**(1.2)**	**3**	**(0.2)**
Allergy to animal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Anaphylactoid reaction	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Atopy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Autoimmune disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cytokine release syndrome	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Drug hypersensitivity	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	1	(0.2)	3	(0.2)	1	(0.1)
Hypersensitivity	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Sarcoidosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Seasonal allergy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**11**	**(2.9)**	**0**	**(0.0)**	**28**	**(3.6)**	**4**	**(0.5)**	**29**	**(6.3)**	**3**	**(0.7)**	**68**	**(4.2)**	**7**	**(0.4)**
Bacterial sepsis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Candida infection	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Clostridium difficile infection	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Conjunctivitis	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)	5	(1.1)	0	(0.0)	10	(0.6)	0	(0.0)
Diverticulitis	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	1	(0.2)	0	(0.0)	3	(0.2)	1	(0.1)
Encephalitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Erysipelas	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Folliculitis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Fungal skin infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastroenteritis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gastroenteritis viral	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Herpes zoster	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	4	(0.2)	0	(0.0)
Hordeolum	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Influenza	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Lung infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Lymph gland infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nasopharyngitis	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Oral candidiasis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**11**	**(2.9)**	**0**	**(0.0)**	**28**	**(3.6)**	**4**	**(0.5)**	**29**	**(6.3)**	**3**	**(0.7)**	**68**	**(4.2)**	**7**	**(0.4)**
Oral fungal infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oral herpes	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Otitis media	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pharyngitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pneumonia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	1	(0.2)	3	(0.2)	1	(0.1)
Respiratory tract infection	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Rhinitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Sinusitis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)
Skin infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Staphylococcal infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tinea versicolour	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tooth abscess	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tuberculosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Upper respiratory tract infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.9)	0	(0.0)	4	(0.2)	0	(0.0)
Urinary tract infection	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**1**	**(0.3)**	**0**	**(0.0)**	**15**	**(2.0)**	**0**	**(0.0)**	**4**	**(0.9)**	**0**	**(0.0)**	**20**	**(1.2)**	**0**	**(0.0)**
Chillblains	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Contusion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Excoriation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Incision site complication	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Infusion related reaction	0	(0.0)	0	(0.0)	9	(1.2)	0	(0.0)	3	(0.7)	0	(0.0)	12	(0.7)	0	(0.0)
Procedural pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Radiation skin injury	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sunburn	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tooth fracture	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Investigations	**55**	**(14.4)**	**5**	**(1.3)**	**91**	**(11.8)**	**8**	**(1.0)**	**67**	**(14.6)**	**4**	**(0.9)**	**213**	**(13.2)**	**17**	**(1.1)**
Activated partial thromboplastin time prolonged	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Alanine aminotransferase	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**55**	**(14.4)**	**5**	**(1.3)**	**91**	**(11.8)**	**8**	**(1.0)**	**67**	**(14.6)**	**4**	**(0.9)**	**213**	**(13.2)**	**17**	**(1.1)**
Alanine aminotransferase increased	13	(3.4)	0	(0.0)	21	(2.7)	3	(0.4)	20	(4.4)	0	(0.0)	54	(3.4)	3	(0.2)
Amylase increased	3	(0.8)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	1	(0.1)
Aortic bruit	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Aspartate aminotransferase increased	14	(3.7)	1	(0.3)	19	(2.5)	4	(0.5)	22	(4.8)	0	(0.0)	55	(3.4)	5	(0.3)
Autoantibody positive	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Bilirubin conjugated increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood alkaline phosphatase decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood alkaline phosphatase increased	2	(0.5)	0	(0.0)	7	(0.9)	0	(0.0)	6	(1.3)	0	(0.0)	15	(0.9)	0	(0.0)
Blood bicarbonate decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood bilirubin increased	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	10	(2.2)	0	(0.0)	16	(1.0)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**55**	**(14.4)**	**5**	**(1.3)**	**91**	**(11.8)**	**8**	**(1.0)**	**67**	**(14.6)**	**4**	**(0.9)**	**213**	**(13.2)**	**17**	**(1.1)**
Blood calcium increased	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Blood cholesterol increased	2	(0.5)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Blood corticotrophin decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Blood corticotrophin increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood cortisol decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Blood creatine phosphokinase increased	3	(0.8)	1	(0.3)	1	(0.1)	1	(0.1)	1	(0.2)	0	(0.0)	5	(0.3)	2	(0.1)
Blood creatinine increased	1	(0.3)	0	(0.0)	7	(0.9)	0	(0.0)	8	(1.7)	0	(0.0)	16	(1.0)	0	(0.0)
Blood glucose abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood glucose increased	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	1	(0.2)	0	(0.0)	2	(0.1)	1	(0.1)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**55**	**(14.4)**	**5**	**(1.3)**	**91**	**(11.8)**	**8**	**(1.0)**	**67**	**(14.6)**	**4**	**(0.9)**	**213**	**(13.2)**	**17**	**(1.1)**
Blood lactate dehydrogenase increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	5	(1.1)	1	(0.2)	5	(0.3)	1	(0.1)
Blood luteinising hormone decreased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Blood parathyroid hormone increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood phosphorus decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood testosterone decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood thyroid stimulating hormone decreased	3	(0.8)	0	(0.0)	8	(1.0)	0	(0.0)	3	(0.7)	0	(0.0)	14	(0.9)	0	(0.0)
Blood thyroid stimulating hormone increased	3	(0.8)	0	(0.0)	7	(0.9)	0	(0.0)	2	(0.4)	0	(0.0)	12	(0.7)	0	(0.0)
Blood triglycerides increased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**55**	**(14.4)**	**5**	**(1.3)**	**91**	**(11.8)**	**8**	**(1.0)**	**67**	**(14.6)**	**4**	**(0.9)**	**213**	**(13.2)**	**17**	**(1.1)**
Blood urea increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Blood uric acid increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Blood urine	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Body temperature increased	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
C-reactive protein increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Electrocardiogram QT prolonged	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Electrocardiogram repolarisation abnormality	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Eosinophil count increased	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Gamma-glutamyltransferase increased	3	(0.8)	2	(0.5)	2	(0.3)	1	(0.1)	3	(0.7)	1	(0.2)	8	(0.5)	4	(0.2)
Haemoglobin decreased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hepatic enzyme increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**55**	**(14.4)**	**5**	**(1.3)**	**91**	**(11.8)**	**8**	**(1.0)**	**67**	**(14.6)**	**4**	**(0.9)**	**213**	**(13.2)**	**17**	**(1.1)**
Lipase	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lipase increased	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Liver function test abnormal	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Lymphocyte count decreased	3	(0.8)	1	(0.3)	5	(0.7)	1	(0.1)	3	(0.7)	0	(0.0)	11	(0.7)	2	(0.1)
Neutrophil count decreased	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Neutrophil count increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Platelet count decreased	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)	3	(0.7)	0	(0.0)	8	(0.5)	0	(0.0)
Thyroglobulin increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroid function test abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Thyroxine decreased	1	(0.3)	0	(0.0)	6	(0.8)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Thyroxine free increased	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Thyroxine increased	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	**55**	**(14.4)**	**5**	**(1.3)**	**91**	**(11.8)**	**8**	**(1.0)**	**67**	**(14.6)**	**4**	**(0.9)**	**213**	**(13.2)**	**17**	**(1.1)**
Transaminases increased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Tri-iodothyronine decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Tri-iodothyronine increased	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	5	(0.3)	0	(0.0)
Weight decreased	5	(1.3)	0	(0.0)	15	(2.0)	0	(0.0)	7	(1.5)	0	(0.0)	27	(1.7)	0	(0.0)
Weight increased	3	(0.8)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
White blood cell count decreased	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
White blood cell count increased	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Metabolism and nutrition disorders	**41**	**(10.7)**	**4**	**(1.0)**	**85**	**(11.1)**	**11**	**(1.4)**	**60**	**(13.1)**	**10**	**(2.2)**	**186**	**(11.6)**	**25**	**(1.6)**
Cell death	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Decreased appetite	24	(6.3)	0	(0.0)	54	(7.0)	2	(0.3)	39	(8.5)	1	(0.2)	117	(7.3)	3	(0.2)
Dehydration	3	(0.8)	1	(0.3)	5	(0.7)	0	(0.0)	5	(1.1)	1	(0.2)	13	(0.8)	2	(0.1)
Diabetes mellitus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Electrolyte imbalance	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Failure to thrive	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**41**	**(10.7)**	**4**	**(1.0)**	**85**	**(11.1)**	**11**	**(1.4)**	**60**	**(13.1)**	**10**	**(2.2)**	**186**	**(11.6)**	**25**	**(1.6)**
Fluid overload	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Fluid retention	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Gout	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypercalcaemia	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Hypercholesterolaemia	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Hyperglycaemia	3	(0.8)	1	(0.3)	4	(0.5)	1	(0.1)	2	(0.4)	1	(0.2)	9	(0.6)	3	(0.2)
Hyperkalaemia	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hyperlipidaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hypertriglyceridaemia	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)	2	(0.4)	1	(0.2)	8	(0.5)	1	(0.1)
Hyperuricaemia	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Hypoalbuminaemia	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)	2	(0.4)	1	(0.2)	4	(0.2)	2	(0.1)
Hypocalcaemia	1	(0.3)	0	(0.0)	7	(0.9)	0	(0.0)	6	(1.3)	0	(0.0)	14	(0.9)	0	(0.0)
Hypokalaemia	0	(0.0)	0	(0.0)	8	(1.0)	2	(0.3)	4	(0.9)	4	(0.9)	12	(0.7)	6	(0.4)
Hypomagnesaemia	0	(0.0)	0	(0.0)	5	(0.7)	0	(0.0)	4	(0.9)	0	(0.0)	9	(0.6)	0	(0.0)
Hyponatraemia	2	(0.5)	0	(0.0)	5	(0.7)	5	(0.7)	1	(0.2)	1	(0.2)	8	(0.5)	6	(0.4)
Hypophosphataemia	3	(0.8)	0	(0.0)	4	(0.5)	0	(0.0)	3	(0.7)	1	(0.2)	10	(0.6)	1	(0.1)
Increased appetite	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**41**	**(10.7)**	**4**	**(1.0)**	**85**	**(11.1)**	**11**	**(1.4)**	**60**	**(13.1)**	**10**	**(2.2)**	**186**	**(11.6)**	**25**	**(1.6)**
Insulin resistant diabetes	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Iron deficiency	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Metabolic disorder	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	2	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Vitamin B12 deficiency	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Musculoskeletal and connective tissue disorders	**72**	**(18.8)**	**4**	**(1.0)**	**159**	**(20.7)**	**5**	**(0.7)**	**116**	**(25.3)**	**3**	**(0.7)**	**347**	**(21.6)**	**12**	**(0.7)**
Ankylosing spondylitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Arthralgia	41	(10.7)	1	(0.3)	93	(12.1)	2	(0.3)	56	(12.2)	0	(0.0)	190	(11.8)	3	(0.2)
Arthritis	3	(0.8)	0	(0.0)	4	(0.5)	0	(0.0)	10	(2.2)	0	(0.0)	17	(1.1)	0	(0.0)
Arthropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Back pain	7	(1.8)	0	(0.0)	12	(1.6)	0	(0.0)	11	(2.4)	0	(0.0)	30	(1.9)	0	(0.0)
Bone pain	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	4	(0.9)	0	(0.0)	6	(0.4)	0	(0.0)
Chondrocalcinosis pyrophosphate	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**72**	**(18.8)**	**4**	**(1.0)**	**159**	**(20.7)**	**5**	**(0.7)**	**116**	**(25.3)**	**3**	**(0.7)**	**347**	**(21.6)**	**12**	**(0.7)**
Fibromyalgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Flank pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Groin pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Growing pains	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Joint effusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Joint range of motion decreased	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Joint stiffness	3	(0.8)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	9	(0.6)	0	(0.0)
Joint swelling	2	(0.5)	0	(0.0)	5	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Limb discomfort	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle atrophy	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle spasms	6	(1.6)	0	(0.0)	9	(1.2)	0	(0.0)	7	(1.5)	0	(0.0)	22	(1.4)	0	(0.0)
Muscle tightness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Muscle twitching	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Muscular weakness	7	(1.8)	2	(0.5)	10	(1.3)	0	(0.0)	3	(0.7)	0	(0.0)	20	(1.2)	2	(0.1)
Musculoskeletal chest pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Musculoskeletal discomfort	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Musculoskeletal pain	2	(0.5)	0	(0.0)	8	(1.0)	1	(0.1)	4	(0.9)	0	(0.0)	14	(0.9)	1	(0.1)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**72**	**(18.8)**	**4**	**(1.0)**	**159**	**(20.7)**	**5**	**(0.7)**	**116**	**(25.3)**	**3**	**(0.7)**	**347**	**(21.6)**	**12**	**(0.7)**
Musculoskeletal stiffness	3	(0.8)	0	(0.0)	10	(1.3)	0	(0.0)	6	(1.3)	0	(0.0)	19	(1.2)	0	(0.0)
Myalgia	19	(5.0)	2	(0.5)	39	(5.1)	0	(0.0)	43	(9.4)	1	(0.2)	101	(6.3)	3	(0.2)
Myopathy	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Myositis	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Neck pain	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Nodal osteoarthritis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Osteoarthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pain in extremity	4	(1.0)	0	(0.0)	11	(1.4)	1	(0.1)	15	(3.3)	1	(0.2)	30	(1.9)	2	(0.1)
Pain in jaw	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	5	(0.3)	0	(0.0)
Plantar fasciitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Polyarthritis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	4	(0.2)	0	(0.0)
Polymyalgia rheumatica	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Rhabdomyolysis	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Rheumatoid arthritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sjogren's syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Spinal pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Synovitis	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Tendon pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**72**	**(18.8)**	**4**	**(1.0)**	**159**	**(20.7)**	**5**	**(0.7)**	**116**	**(25.3)**	**3**	**(0.7)**	**347**	**(21.6)**	**12**	**(0.7)**
Tendonitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Tenosynovitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Torticollis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**3**	**(0.8)**	**0**	**(0.0)**	**9**	**(1.2)**	**0**	**(0.0)**	**5**	**(1.1)**	**0**	**(0.0)**	**17**	**(1.1)**	**0**	**(0.0)**
Acrochordon	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Infected neoplasm	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Keratoacanthoma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Malignant melanoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Melanocytic naevus	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Metastatic pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neoplasm swelling	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Oncologic complication	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Seborrhoeic keratosis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Skin papilloma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**3**	**(0.8)**	**0**	**(0.0)**	**9**	**(1.2)**	**0**	**(0.0)**	**5**	**(1.1)**	**0**	**(0.0)**	**17**	**(1.1)**	**0**	**(0.0)**
Tumour pain	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	6	(0.4)	0	(0.0)
Nervous system disorders	**50**	**(13.1)**	**3**	**(0.8)**	**85**	**(11.1)**	**5**	**(0.7)**	**72**	**(15.7)**	**3**	**(0.7)**	**207**	**(12.9)**	**11**	**(0.7)**
Ageusia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Amnesia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Amnestic disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Balance disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.7)	0	(0.0)	3	(0.2)	0	(0.0)
Brain oedema	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Carpal tunnel syndrome	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Cerebral haemorrhage	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Cognitive disorder	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Depressed level of consciousness	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Disturbance in attention	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Dizziness	4	(1.0)	0	(0.0)	5	(0.7)	0	(0.0)	16	(3.5)	0	(0.0)	25	(1.6)	0	(0.0)
Dysaesthesia	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**50**	**(13.1)**	**3**	**(0.8)**	**85**	**(11.1)**	**5**	**(0.7)**	**72**	**(15.7)**	**3**	**(0.7)**	**207**	**(12.9)**	**11**	**(0.7)**
Dysarthria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dysgeusia	7	(1.8)	0	(0.0)	14	(1.8)	0	(0.0)	11	(2.4)	0	(0.0)	32	(2.0)	0	(0.0)
Encephalopathy	2	(0.5)	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	2	(0.1)
Epilepsy	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	2	(0.4)	2	(0.4)	3	(0.2)	3	(0.2)
Guillain-Barre syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Haemorrhagic stroke	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Headache	16	(4.2)	1	(0.3)	35	(4.6)	1	(0.1)	27	(5.9)	0	(0.0)	78	(4.8)	2	(0.1)
Hyperaesthesia	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hypersomnia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hypoaesthesia	4	(1.0)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	9	(0.6)	0	(0.0)
Hypogeusia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Hypotonia	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Judgement impaired	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lethargy	5	(1.3)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	10	(0.6)	0	(0.0)
Loss of consciousness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Memory impairment	3	(0.8)	0	(0.0)	3	(0.4)	0	(0.0)	4	(0.9)	0	(0.0)	10	(0.6)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**50**	**(13.1)**	**3**	**(0.8)**	**85**	**(11.1)**	**5**	**(0.7)**	**72**	**(15.7)**	**3**	**(0.7)**	**207**	**(12.9)**	**11**	**(0.7)**
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Neuralgia	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Neuropathy peripheral	3	(0.8)	0	(0.0)	6	(0.8)	0	(0.0)	6	(1.3)	0	(0.0)	15	(0.9)	0	(0.0)
Optic neuritis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Paraesthesia	2	(0.5)	0	(0.0)	9	(1.2)	0	(0.0)	3	(0.7)	0	(0.0)	14	(0.9)	0	(0.0)
Parosmia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Partial seizures	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral sensory neuropathy	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Polyneuropathy	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Poor quality sleep	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Presyncope	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Restless legs syndrome	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Sciatica	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Seizure	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**50**	**(13.1)**	**3**	**(0.8)**	**85**	**(11.1)**	**5**	**(0.7)**	**72**	**(15.7)**	**3**	**(0.7)**	**207**	**(12.9)**	**11**	**(0.7)**
Sensory disturbance	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Syncope	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tremor	4	(1.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Psychiatric disorders	**6**	**(1.6)**	**1**	**(0.3)**	**20**	**(2.6)**	**0**	**(0.0)**	**18**	**(3.9)**	**0**	**(0.0)**	**44**	**(2.7)**	**1**	**(0.1)**
Affective disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Agitation	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Anxiety	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Confusional state	1	(0.3)	1	(0.3)	3	(0.4)	0	(0.0)	4	(0.9)	0	(0.0)	8	(0.5)	1	(0.1)
Depression	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	4	(0.9)	0	(0.0)	5	(0.3)	0	(0.0)
Disorientation	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Dysphoria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hallucination	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Insomnia	2	(0.5)	0	(0.0)	6	(0.8)	0	(0.0)	8	(1.7)	0	(0.0)	16	(1.0)	0	(0.0)
Irritability	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Libido decreased	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Middle insomnia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Phobia	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sleep disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Trance	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Renal and urinary disorders	**3**	**(0.8)**	**0**	**(0.0)**	**9**	**(1.2)**	**1**	**(0.1)**	**11**	**(2.4)**	**3**	**(0.7)**	**23**	**(1.4)**	**4**	**(0.2)**
Acute kidney injury	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	2	(0.4)	4	(0.2)	2	(0.1)
Chromaturia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Chronic kidney disease	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Dysuria	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Haematuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Pollakiuria	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	3	(0.7)	0	(0.0)	5	(0.3)	0	(0.0)
Proteinuria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	3	(0.4)	1	(0.1)	2	(0.4)	1	(0.2)	5	(0.3)	2	(0.1)
Renal impairment	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Tubulointerstitial nephritis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Urinary incontinence	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Urine odour abnormal	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Reproductive system and breast disorders	**6**	**(1.6)**	**1**	**(0.3)**	**9**	**(1.2)**	**0**	**(0.0)**	**5**	**(1.1)**	**0**	**(0.0)**	**20**	**(1.2)**	**1**	**(0.1)**
Amenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Breast pain	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Reproductive system and breast disorders	**6**	**(1.6)**	**1**	**(0.3)**	**9**	**(1.2)**	**0**	**(0.0)**	**5**	**(1.1)**	**0**	**(0.0)**	**20**	**(1.2)**	**1**	**(0.1)**
Breast tenderness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dysmenorrhoea	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erectile dysfunction	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Genital rash	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Haematospermia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Menorrhagia	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Nipple pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Nipple swelling	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pelvic pain	2	(0.5)	1	(0.3)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	1	(0.1)
Prostatic obstruction	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pruritus genital	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Scrotal erythema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vulvovaginal pruritus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**54**	**(14.1)**	**5**	**(1.3)**	**90**	**(11.7)**	**7**	**(0.9)**	**54**	**(11.8)**	**3**	**(0.7)**	**198**	**(12.3)**	**15**	**(0.9)**
Asthma	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**54**	**(14.1)**	**5**	**(1.3)**	**90**	**(11.7)**	**7**	**(0.9)**	**54**	**(11.8)**	**3**	**(0.7)**	**198**	**(12.3)**	**15**	**(0.9)**
Bronchial hyperreactivity	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Cough	23	(6.0)	0	(0.0)	39	(5.1)	0	(0.0)	21	(4.6)	1	(0.2)	83	(5.2)	1	(0.1)
Dysphonia	2	(0.5)	1	(0.3)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	1	(0.1)
Dyspnoea	18	(4.7)	3	(0.8)	32	(4.2)	3	(0.4)	16	(3.5)	0	(0.0)	66	(4.1)	6	(0.4)
Dyspnoea exertional	4	(1.0)	0	(0.0)	4	(0.5)	0	(0.0)	4	(0.9)	0	(0.0)	12	(0.7)	0	(0.0)
Epistaxis	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Haemoptysis	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Hiccups	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Interstitial lung disease	1	(0.3)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Laryngeal discomfort	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Laryngeal inflammation	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Nasal congestion	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	1	(0.2)	0	(0.0)	6	(0.4)	0	(0.0)
Nasal dryness	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**54**	**(14.1)**	**5**	**(1.3)**	**90**	**(11.7)**	**7**	**(0.9)**	**54**	**(11.8)**	**3**	**(0.7)**	**198**	**(12.3)**	**15**	**(0.9)**
Nasal mucosal disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Oropharyngeal pain	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	3	(0.7)	0	(0.0)	8	(0.5)	0	(0.0)
Painful respiration	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Pleural effusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	0	(0.0)	2	(0.1)	0	(0.0)
Pleuritic pain	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	1	(0.2)	3	(0.2)	1	(0.1)
Pneumonitis	4	(1.0)	1	(0.3)	15	(2.0)	3	(0.4)	8	(1.7)	1	(0.2)	27	(1.7)	5	(0.3)
Productive cough	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Pulmonary congestion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pulmonary oedema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Respiratory failure	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Respiratory tract congestion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rhinitis allergic	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Rhinorrhoea	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Sinus congestion	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sneezing	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Throat irritation	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Wheezing	2	(0.5)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**166**	**(43.5)**	**3**	**(0.8)**	**347**	**(45.1)**	**7**	**(0.9)**	**209**	**(45.6)**	**7**	**(1.5)**	**722**	**(44.9)**	**17**	**(1.1)**
Acne	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	2	(0.4)	0	(0.0)	4	(0.2)	0	(0.0)
Actinic keratosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Alopecia	7	(1.8)	0	(0.0)	6	(0.8)	0	(0.0)	4	(0.9)	0	(0.0)	17	(1.1)	0	(0.0)
Blister	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	3	(0.7)	0	(0.0)	7	(0.4)	0	(0.0)
Dermatitis acneiform	4	(1.0)	0	(0.0)	5	(0.7)	0	(0.0)	1	(0.2)	0	(0.0)	10	(0.6)	0	(0.0)
Dermatitis allergic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis exfoliative	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Dermatitis psoriasiform	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Drug eruption	1	(0.3)	1	(0.3)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	1	(0.1)
Dry skin	14	(3.7)	0	(0.0)	25	(3.3)	0	(0.0)	10	(2.2)	0	(0.0)	49	(3.0)	0	(0.0)
Eczema	4	(1.0)	0	(0.0)	12	(1.6)	0	(0.0)	7	(1.5)	0	(0.0)	23	(1.4)	0	(0.0)
Eczema asteatotic	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Erythema	11	(2.9)	0	(0.0)	14	(1.8)	0	(0.0)	12	(2.6)	0	(0.0)	37	(2.3)	0	(0.0)
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Erythema nodosum	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**166**	**(43.5)**	**3**	**(0.8)**	**347**	**(45.1)**	**7**	**(0.9)**	**209**	**(45.6)**	**7**	**(1.5)**	**722**	**(44.9)**	**17**	**(1.1)**
Exfoliative rash	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Granuloma skin	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hair colour changes	4	(1.0)	0	(0.0)	3	(0.4)	0	(0.0)	8	(1.7)	0	(0.0)	15	(0.9)	0	(0.0)
Hair growth abnormal	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Hair texture abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hyperhidrosis	3	(0.8)	0	(0.0)	5	(0.7)	0	(0.0)	5	(1.1)	0	(0.0)	13	(0.8)	0	(0.0)
Hyperkeratosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Hypertrichosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Ichthyosis acquired	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Keratosis pilaris	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	2	(0.4)	0	(0.0)	3	(0.2)	0	(0.0)
Lichen planus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.4)	1	(0.2)	2	(0.1)	1	(0.1)
Lichen sclerosus	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lichenoid keratosis	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	3	(0.2)	0	(0.0)
Linear IgA disease	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Macule	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Madarosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nail discolouration	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Nail disorder	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**166**	**(43.5)**	**3**	**(0.8)**	**347**	**(45.1)**	**7**	**(0.9)**	**209**	**(45.6)**	**7**	**(1.5)**	**722**	**(44.9)**	**17**	**(1.1)**
Nail growth abnormal	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Neutrophilic dermatosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Night sweats	7	(1.8)	0	(0.0)	11	(1.4)	0	(0.0)	9	(2.0)	0	(0.0)	27	(1.7)	0	(0.0)
Onychoclasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pain of skin	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Palmar-plantar erythrodysaesthesia syndrome	2	(0.5)	0	(0.0)	1	(0.1)	0	(0.0)	3	(0.7)	0	(0.0)	6	(0.4)	0	(0.0)
Panniculitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Papule	3	(0.8)	0	(0.0)	4	(0.5)	0	(0.0)	4	(0.9)	0	(0.0)	11	(0.7)	0	(0.0)
Parapsoriasis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pemphigoid	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	1	(0.2)	1	(0.1)	1	(0.1)
Photosensitivity reaction	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Pigmentation disorder	2	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Prurigo	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Pruritus	82	(21.5)	0	(0.0)	160	(20.8)	1	(0.1)	84	(18.3)	1	(0.2)	326	(20.3)	2	(0.1)
Pruritus generalised	2	(0.5)	0	(0.0)	9	(1.2)	0	(0.0)	4	(0.9)	0	(0.0)	15	(0.9)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**166**	**(43.5)**	**3**	**(0.8)**	**347**	**(45.1)**	**7**	**(0.9)**	**209**	**(45.6)**	**7**	**(1.5)**	**722**	**(44.9)**	**17**	**(1.1)**
Psoriasis	0	(0.0)	0	(0.0)	3	(0.4)	0	(0.0)	3	(0.7)	1	(0.2)	6	(0.4)	1	(0.1)
Purpura	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Pustular psoriasis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Rash	59	(15.4)	0	(0.0)	117	(15.2)	1	(0.1)	74	(16.2)	1	(0.2)	250	(15.5)	2	(0.1)
Rash erythematous	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	6	(1.3)	1	(0.2)	10	(0.6)	1	(0.1)
Rash follicular	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Rash generalised	3	(0.8)	0	(0.0)	6	(0.8)	1	(0.1)	4	(0.9)	0	(0.0)	13	(0.8)	1	(0.1)
Rash macular	1	(0.3)	0	(0.0)	4	(0.5)	0	(0.0)	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Rash maculo-papular	15	(3.9)	1	(0.3)	28	(3.6)	3	(0.4)	14	(3.1)	0	(0.0)	57	(3.5)	4	(0.2)
Rash papular	2	(0.5)	0	(0.0)	5	(0.7)	0	(0.0)	0	(0.0)	0	(0.0)	7	(0.4)	0	(0.0)
Rash pruritic	2	(0.5)	0	(0.0)	7	(0.9)	0	(0.0)	8	(1.7)	1	(0.2)	17	(1.1)	1	(0.1)
Rash vesicular	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	2	(0.1)	0	(0.0)
Rosacea	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Scab	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Sebaceous gland disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Seborrhoeic dermatitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin burning sensation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**166**	**(43.5)**	**3**	**(0.8)**	**347**	**(45.1)**	**7**	**(0.9)**	**209**	**(45.6)**	**7**	**(1.5)**	**722**	**(44.9)**	**17**	**(1.1)**
Skin depigmentation	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Skin discolouration	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Skin disorder	0	(0.0)	0	(0.0)	4	(0.5)	0	(0.0)	0	(0.0)	0	(0.0)	4	(0.2)	0	(0.0)
Skin exfoliation	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Skin haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Skin hyperpigmentation	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	1	(0.2)	0	(0.0)	5	(0.3)	0	(0.0)
Skin hypopigmentation	5	(1.3)	0	(0.0)	15	(2.0)	0	(0.0)	7	(1.5)	0	(0.0)	27	(1.7)	0	(0.0)
Skin irritation	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Skin lesion	1	(0.3)	0	(0.0)	5	(0.7)	0	(0.0)	2	(0.4)	0	(0.0)	8	(0.5)	0	(0.0)
Skin mass	1	(0.3)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	4	(0.2)	0	(0.0)
Skin ulcer	1	(0.3)	0	(0.0)	1	(0.1)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Solar dermatitis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Stevens-Johnson syndrome	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Toxic skin eruption	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin and subcutaneous tissue disorders	**166**	**(43.5)**	**3**	**(0.8)**	**347**	**(45.1)**	**7**	**(0.9)**	**209**	**(45.6)**	**7**	**(1.5)**	**722**	**(44.9)**	**17**	**(1.1)**
Transient acantholytic dermatosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Urticaria	2	(0.5)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	7	(0.4)	0	(0.0)
Urticaria papular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Vitiligo	28	(7.3)	0	(0.0)	70	(9.1)	0	(0.0)	49	(10.7)	0	(0.0)	147	(9.1)	0	(0.0)
Xanthelasma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Xeroderma	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	2	(0.1)	0	(0.0)
Vascular disorders	**7**	**(1.8)**	**1**	**(0.3)**	**21**	**(2.7)**	**1**	**(0.1)**	**19**	**(4.1)**	**2**	**(0.4)**	**47**	**(2.9)**	**4**	**(0.2)**
Flushing	0	(0.0)	0	(0.0)	6	(0.8)	0	(0.0)	4	(0.9)	0	(0.0)	10	(0.6)	0	(0.0)
Haematoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Hot flush	3	(0.8)	0	(0.0)	6	(0.8)	0	(0.0)	6	(1.3)	0	(0.0)	15	(0.9)	0	(0.0)
Hypertension	1	(0.3)	0	(0.0)	2	(0.3)	1	(0.1)	3	(0.7)	2	(0.4)	6	(0.4)	3	(0.2)
Hypotension	0	(0.0)	0	(0.0)	2	(0.3)	0	(0.0)	1	(0.2)	0	(0.0)	3	(0.2)	0	(0.0)
Intermittent claudication	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Jugular vein thrombosis	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Lymphoedema	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Pallor	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)

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付録 2.7.4-18 副作用（いずれかの投与群で発現割合 0%超）

001 試験+002 試験+006 試験+041 試験（APaT 集団）（続き）

	MK-3475 2 mg/kg Q3W				MK-3475 10 mg/kg Q3W				MK-3475 10 mg/kg Q2W				Total			
	All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5		All Grades		Grades 3 – 5	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**7**	**(1.8)**	**1**	**(0.3)**	**21**	**(2.7)**	**1**	**(0.1)**	**19**	**(4.1)**	**2**	**(0.4)**	**47**	**(2.9)**	**4**	**(0.2)**
Peripheral coldness	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.2)	0	(0.0)	1	(0.1)	0	(0.0)
Peripheral ischaemia	1	(0.3)	1	(0.3)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	1	(0.1)
Raynaud's phenomenon	1	(0.3)	0	(0.0)	3	(0.4)	0	(0.0)	2	(0.4)	0	(0.0)	6	(0.4)	0	(0.0)
Varicophlebitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Vasculitis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)
Venous thrombosis	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.1)	0	(0.0)

Every subject is counted a single time for each applicable row and column.

A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.

MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.

Grades are based on NCI CTCAE version 4.0.

Adverse event terms are from MedDRA Version 18.0.

(MK-3475 KN-001 Database Cutoff Date: [redacted].

(MK-3475 KN-002 Database Cutoff Date: 12MAY2014).

(MK-3475 KN-006 Database Cutoff Date: 03SEP2014).

(MK-3475 KN-041 Database Cutoff Date: [redacted].

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付録 2.7.4-19 死亡に至ったすべての有害事象（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Subjects in population	171		178		179	
with one or more adverse events	11	(6.4)	13	(7.3)	8	(4.5)
with no adverse events	160	(93.6)	165	(92.7)	171	(95.5)
Gastrointestinal disorders	**0**	**(0.0)**	**1**	**(0.6)**	**1**	**(0.6)**
Intestinal obstruction	0	(0.0)	1	(0.6)	0	(0.0)
Upper gastrointestinal haemorrhage	0	(0.0)	0	(0.0)	1	(0.6)
General disorders and administration site conditions	**6**	**(3.5)**	**5**	**(2.8)**	**4**	**(2.2)**
Death	2	(1.2)	3	(1.7)	2	(1.1)
General physical health deterioration	3	(1.8)	1	(0.6)	2	(1.1)
Generalised oedema	1	(0.6)	1	(0.6)	0	(0.0)
Hepatobiliary disorders	**0**	**(0.0)**	**1**	**(0.6)**	**1**	**(0.6)**
Hepatic failure	0	(0.0)	1	(0.6)	1	(0.6)
Infections and infestations	**2**	**(1.2)**	**2**	**(1.1)**	**0**	**(0.0)**
Atypical pneumonia	1	(0.6)	0	(0.0)	0	(0.0)
Infectious pleural effusion	0	(0.0)	1	(0.6)	0	(0.0)
Pneumonia	1	(0.6)	0	(0.0)	0	(0.0)
Septic shock	0	(0.0)	1	(0.6)	0	(0.0)
Injury, poisoning and procedural complications	**1**	**(0.6)**	**0**	**(0.0)**	**0**	**(0.0)**
Subdural haematoma	1	(0.6)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders	**0**	**(0.0)**	**1**	**(0.6)**	**0**	**(0.0)**
Cachexia	0	(0.0)	1	(0.6)	0	(0.0)
Nervous system disorders	**1**	**(0.6)**	**0**	**(0.0)**	**0**	**(0.0)**
Haemorrhage intracranial	1	(0.6)	0	(0.0)	0	(0.0)
Psychiatric disorders	**0**	**(0.0)**	**1**	**(0.6)**	**0**	**(0.0)**
Mental status changes	0	(0.0)	1	(0.6)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**1**	**(0.6)**	**1**	**(0.6)**	**2**	**(1.1)**
Dyspnoea	0	(0.0)	0	(0.0)	2	(1.1)
Haemothorax	0	(0.0)	1	(0.6)	0	(0.0)

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付録 2.7.4-19 死亡に至ったすべての有害事象（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）（続き）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**1**	**(0.6)**	**1**	**(0.6)**	**2**	**(1.1)**
Pulmonary embolism	1	(0.6)	0	(0.0)	0	(0.0)
Vascular disorders	**0**	**(0.0)**	**1**	**(0.6)**	**0**	**(0.0)**
Haemorrhagic infarction	0	(0.0)	1	(0.6)	0	(0.0)

Every subject is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.
(Database Cutoff Date: 12MAY2014).

Data Source: [資料5.3.5.1.1: P002V01]

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付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）

	Ipi-naïve 2 mg/kg Q3W		Ipi-naïve 10 mg/kg Q3W		Ipi-exposed 2 mg/kg Q3W		Ipi-exposed 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)	n	(%)
Patients in population	51		52		89		84	
with one or more adverse events	15	(29.4)	21	(40.4)	31	(34.8)	33	(39.3)
with no adverse events	36	(70.6)	31	(59.6)	58	(65.2)	51	(60.7)
Blood and lymphatic system disorders	**1**	**(2.0)**	**1**	**(1.9)**	**0**	**(0.0)**	**1**	**(1.2)**
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Leukocytosis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Thrombocytopenia	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cardiac disorders	**4**	**(7.8)**	**2**	**(3.8)**	**1**	**(1.1)**	**1**	**(1.2)**
Atrial fibrillation	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Atrial flutter	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Atrial thrombosis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Cardiac failure congestive	2	(3.9)	0	(0.0)	0	(0.0)	1	(1.2)
Pericardial effusion	2	(3.9)	0	(0.0)	0	(0.0)	0	(0.0)
Pericarditis	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Tachycardia	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Endocrine disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(2.2)**	**1**	**(1.2)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Hyperthyroidism	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Hypophysitis	0	(0.0)	0	(0.0)	2	(2.2)	0	(0.0)
Eye disorders	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(1.2)**
Visual acuity reduced	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Gastrointestinal disorders	**7**	**(13.7)**	**7**	**(13.5)**	**3**	**(3.4)**	**9**	**(10.7)**
Abdominal pain	1	(2.0)	1	(1.9)	0	(0.0)	4	(4.8)
Ascites	0	(0.0)	0	(0.0)	1	(1.1)	1	(1.2)
Colitis	1	(2.0)	2	(3.8)	0	(0.0)	0	(0.0)
Constipation	0	(0.0)	0	(0.0)	1	(1.1)	3	(3.6)
Diarrhoea	2	(3.9)	0	(0.0)	0	(0.0)	1	(1.2)
Gastric ulcer haemorrhage	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Gastritis	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Gastrointestinal haemorrhage	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)

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付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Total	
	n	(%)
Patients in population	276	
with one or more adverse events	100	(36.2)
with no adverse events	176	(63.8)
Blood and lymphatic system disorders	**3**	**(1.1)**
Anaemia	1	(0.4)
Leukocytosis	1	(0.4)
Thrombocytopenia	1	(0.4)
Cardiac disorders	**8**	**(2.9)**
Atrial fibrillation	1	(0.4)
Atrial flutter	1	(0.4)
Atrial thrombosis	1	(0.4)
Cardiac failure congestive	3	(1.1)
Pericardial effusion	2	(0.7)
Pericarditis	1	(0.4)
Tachycardia	1	(0.4)
Endocrine disorders	**3**	**(1.1)**
Adrenal insufficiency	1	(0.4)
Hyperthyroidism	1	(0.4)
Hypophysitis	2	(0.7)
Eye disorders	**1**	**(0.4)**
Visual acuity reduced	1	(0.4)
Gastrointestinal disorders	**26**	**(9.4)**
Abdominal pain	6	(2.2)
Ascites	2	(0.7)
Colitis	3	(1.1)
Constipation	4	(1.4)
Diarrhoea	3	(1.1)
Gastric ulcer haemorrhage	1	(0.4)
Gastritis	1	(0.4)
Gastrointestinal haemorrhage	1	(0.4)

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001 試験パート B2+D（APaT 集団）（続き）

	Ipi-naïve 2 mg/kg Q3W		Ipi-naïve 10 mg/kg Q3W		Ipi-exposed 2 mg/kg Q3W		Ipi-exposed 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	7	**(13.7)**	7	**(13.5)**	**3**	**(3.4)**	**9**	**(10.7)**
Intestinal obstruction	1	(2.0)	0	(0.0)	0	(0.0)	1	(1.2)
Nausea	1	(2.0)	1	(1.9)	0	(0.0)	1	(1.2)
Oesophagitis	1	(2.0)	1	(1.9)	0	(0.0)	0	(0.0)
Pancreatitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Retroperitoneal haemorrhage	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Small intestinal obstruction	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Vomiting	2	(3.9)	1	(1.9)	0	(0.0)	0	(0.0)
General disorders and administration site conditions	**4**	**(7.8)**	**3**	**(5.8)**	**2**	**(2.2)**	**4**	**(4.8)**
Asthenia	1	(2.0)	1	(1.9)	0	(0.0)	1	(1.2)
Chills	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Fatigue	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
General physical health deterioration	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Generalised oedema	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Impaired healing	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Malaise	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Non-cardiac chest pain	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Pain	0	(0.0)	0	(0.0)	0	(0.0)	2	(2.4)
Pyrexia	2	(3.9)	1	(1.9)	0	(0.0)	0	(0.0)
Hepatobiliary disorders	**1**	**(2.0)**	**0**	**(0.0)**	**1**	**(1.1)**	**1**	**(1.2)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Bile duct obstruction	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cholecystitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Infections and infestations	**3**	**(5.9)**	**9**	**(17.3)**	**9**	**(10.1)**	**6**	**(7.1)**
Bronchitis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Catheter site infection	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Cellulitis	0	(0.0)	3	(5.8)	0	(0.0)	2	(2.4)
Diverticulitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Erysipelas	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Lung infection	0	(0.0)	1	(1.9)	1	(1.1)	0	(0.0)
Pneumonia	1	(2.0)	1	(1.9)	4	(4.5)	1	(1.2)

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付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Total	
	n	(%)
Gastrointestinal disorders	**26**	**(9.4)**
Intestinal obstruction	2	(0.7)
Nausea	3	(1.1)
Oesophagitis	2	(0.7)
Pancreatitis	1	(0.4)
Retroperitoneal haemorrhage	1	(0.4)
Small intestinal obstruction	1	(0.4)
Vomiting	3	(1.1)
General disorders and administration site conditions	**13**	**(4.7)**
Asthenia	3	(1.1)
Chills	1	(0.4)
Fatigue	1	(0.4)
General physical health deterioration	1	(0.4)
Generalised oedema	1	(0.4)
Impaired healing	1	(0.4)
Malaise	1	(0.4)
Non-cardiac chest pain	1	(0.4)
Pain	2	(0.7)
Pyrexia	3	(1.1)
Hepatobiliary disorders	**3**	**(1.1)**
Autoimmune hepatitis	1	(0.4)
Bile duct obstruction	1	(0.4)
Cholecystitis	1	(0.4)
Infections and infestations	**27**	**(9.8)**
Bronchitis	1	(0.4)
Catheter site infection	1	(0.4)
Cellulitis	5	(1.8)
Diverticulitis	1	(0.4)
Erysipelas	1	(0.4)
Lung infection	2	(0.7)
Pneumonia	7	(2.5)

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001 試験パート B2+D（APaT 集団）（続き）

	Ipi-naïve 2 mg/kg Q3W		Ipi-naïve 10 mg/kg Q3W		Ipi-exposed 2 mg/kg Q3W		Ipi-exposed 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)	n	(%)
Infections and infestations	**3**	**(5.9)**	**9**	**(17.3)**	**9**	**(10.1)**	**6**	**(7.1)**
Sepsis	0	(0.0)	0	(0.0)	1	(1.1)	1	(1.2)
Septic shock	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Skin infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Tuberculosis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Upper respiratory tract infection	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Urinary tract infection	0	(0.0)	2	(3.8)	1	(1.1)	1	(1.2)
Wound infection	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Injury, poisoning and procedural complications	**0**	**(0.0)**	**1**	**(1.9)**	**0**	**(0.0)**	**2**	**(2.4)**
Femoral neck fracture	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Hip fracture	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Humerus fracture	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Investigations	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(2.4)**
Bilirubin conjugated increased	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Electrocardiogram change	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Metabolism and nutrition disorders	**4**	**(7.8)**	**5**	**(9.6)**	**5**	**(5.6)**	**5**	**(6.0)**
Decreased appetite	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Dehydration	1	(2.0)	1	(1.9)	2	(2.2)	1	(1.2)
Diabetes mellitus	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Electrolyte imbalance	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Failure to thrive	0	(0.0)	0	(0.0)	1	(1.1)	1	(1.2)
Hyperglycaemia	1	(2.0)	0	(0.0)	0	(0.0)	1	(1.2)
Hyperuricaemia	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hypoglycaemia	0	(0.0)	1	(1.9)	0	(0.0)	1	(1.2)
Hyponatraemia	0	(0.0)	1	(1.9)	1	(1.1)	1	(1.2)
Insulin resistant diabetes	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Malnutrition	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)

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付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Total	
	n	(%)
Infections and infestations	**27**	**(9.8)**
Sepsis	2	(0.7)
Septic shock	1	(0.4)
Skin infection	1	(0.4)
Tuberculosis	1	(0.4)
Upper respiratory tract infection	1	(0.4)
Urinary tract infection	4	(1.4)
Wound infection	1	(0.4)
Injury, poisoning and procedural complications	**3**	**(1.1)**
Femoral neck fracture	1	(0.4)
Hip fracture	1	(0.4)
Humerus fracture	1	(0.4)
Investigations	**2**	**(0.7)**
Bilirubin conjugated increased	1	(0.4)
Electrocardiogram change	1	(0.4)
Metabolism and nutrition disorders	**19**	**(6.9)**
Decreased appetite	1	(0.4)
Dehydration	5	(1.8)
Diabetes mellitus	1	(0.4)
Electrolyte imbalance	1	(0.4)
Failure to thrive	2	(0.7)
Hyperglycaemia	2	(0.7)
Hyperuricaemia	1	(0.4)
Hypoglycaemia	2	(0.7)
Hyponatraemia	3	(1.1)
Insulin resistant diabetes	1	(0.4)
Malnutrition	1	(0.4)
Type 1 diabetes mellitus	1	(0.4)

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付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Ipi-naïve 2 mg/kg Q3W		Ipi-naïve 10 mg/kg Q3W		Ipi-exposed 2 mg/kg Q3W		Ipi-exposed 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**2**	**(3.9)**	**1**	**(1.9)**	**1**	**(1.1)**	**2**	**(2.4)**
Back pain	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Muscular weakness	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Musculoskeletal chest pain	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Musculoskeletal pain	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Pain in extremity	1	(2.0)	0	(0.0)	1	(1.1)	0	(0.0)
Spinal pain	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Synovial cyst	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**(2.0)**	**1**	**(1.9)**	**9**	**(10.1)**	**7**	**(8.3)**
Adenocarcinoma	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Basal cell carcinoma	0	(0.0)	1	(1.9)	3	(3.4)	0	(0.0)
Malignant melanoma	0	(0.0)	0	(0.0)	2	(2.2)	0	(0.0)
Metastases to central nervous system	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Metastases to meninges	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Metastatic pain	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Squamous cell carcinoma	0	(0.0)	0	(0.0)	1	(1.1)	2	(2.4)
Tumour haemorrhage	1	(2.0)	0	(0.0)	0	(0.0)	2	(2.4)
Tumour pain	0	(0.0)	0	(0.0)	2	(2.2)	1	(1.2)
Nervous system disorders	**2**	**(3.9)**	**3**	**(5.8)**	**4**	**(4.5)**	**1**	**(1.2)**
Cerebrovascular accident	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dizziness	1	(2.0)	0	(0.0)	0	(0.0)	1	(1.2)
Encephalopathy	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Haemorrhage intracranial	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Ischaemic stroke	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Lethargy	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Neuralgia	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Neuropathy peripheral	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Partial seizures	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)

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（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Total	
	n	(%)
Musculoskeletal and connective tissue disorders	**6**	**(2.2)**
Back pain	1	(0.4)
Muscular weakness	1	(0.4)
Musculoskeletal chest pain	1	(0.4)
Musculoskeletal pain	1	(0.4)
Pain in extremity	2	(0.7)
Spinal pain	1	(0.4)
Synovial cyst	1	(0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**18**	**(6.5)**
Adenocarcinoma	1	(0.4)
Basal cell carcinoma	4	(1.4)
Malignant melanoma	2	(0.7)
Metastases to central nervous system	1	(0.4)
Metastases to meninges	1	(0.4)
Metastatic pain	1	(0.4)
Squamous cell carcinoma	3	(1.1)
Tumour haemorrhage	3	(1.1)
Tumour pain	3	(1.1)
Nervous system disorders	**10**	**(3.6)**
Cerebrovascular accident	1	(0.4)
Dizziness	2	(0.7)
Encephalopathy	1	(0.4)
Haemorrhage intracranial	1	(0.4)
Ischaemic stroke	1	(0.4)
Lethargy	1	(0.4)
Neuralgia	1	(0.4)
Neuropathy peripheral	1	(0.4)
Partial seizures	1	(0.4)

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付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Ipi-naïve 2 mg/kg Q3W		Ipi-naïve 10 mg/kg Q3W		Ipi-exposed 2 mg/kg Q3W		Ipi-exposed 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)	n	(%)
Nervous system disorders	**2**	**(3.9)**	**3**	**(5.8)**	**4**	**(4.5)**	**1**	**(1.2)**
Sciatica	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Spinal cord compression	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Psychiatric disorders	**1**	**(2.0)**	**0**	**(0.0)**	**1**	**(1.1)**	**0**	**(0.0)**
Confusional state	1	(2.0)	0	(0.0)	1	(1.1)	0	(0.0)
Renal and urinary disorders	**0**	**(0.0)**	**3**	**(5.8)**	**0**	**(0.0)**	**3**	**(3.6)**
Hydronephrosis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Renal failure acute	0	(0.0)	2	(3.8)	0	(0.0)	2	(2.4)
Urinary retention	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Reproductive system and breast disorders	**0**	**(0.0)**	**1**	**(1.9)**	**0**	**(0.0)**	**0**	**(0.0)**
Prostatitis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**4**	**(7.8)**	**3**	**(5.8)**	7	**(7.9)**	**3**	**(3.6)**
Atelectasis	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Bronchial obstruction	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Dyspnoea	1	(2.0)	1	(1.9)	4	(4.5)	2	(2.4)
Haemoptysis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Lung consolidation	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pleural effusion	2	(3.9)	0	(0.0)	2	(2.2)	1	(1.2)
Pneumonitis	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Pulmonary embolism	0	(0.0)	2	(3.8)	0	(0.0)	0	(0.0)
Skin and subcutaneous tissue disorders	**1**	**(2.0)**	**1**	**(1.9)**	**1**	**(1.1)**	**0**	**(0.0)**
Haemorrhage subcutaneous	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Rash generalised	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Rash maculo-papular	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vascular disorders	**1**	**(2.0)**	**2**	**(3.8)**	**0**	**(0.0)**	**2**	**(2.4)**

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付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Total	
	n	(%)
Nervous system disorders	**10**	**(3.6)**
Sciatica	1	(0.4)
Spinal cord compression	1	(0.4)
Psychiatric disorders	**2**	**(0.7)**
Confusional state	2	(0.7)
Renal and urinary disorders	**6**	**(2.2)**
Hydronephrosis	1	(0.4)
Renal failure	1	(0.4)
Renal failure acute	4	(1.4)
Urinary retention	1	(0.4)
Reproductive system and breast disorders	**1**	**(0.4)**
Prostatitis	1	(0.4)
Respiratory, thoracic and mediastinal disorders	**17**	**(6.2)**
Atelectasis	1	(0.4)
Bronchial obstruction	1	(0.4)
Dyspnoea	8	(2.9)
Haemoptysis	1	(0.4)
Hypoxia	1	(0.4)
Lung consolidation	1	(0.4)
Pleural effusion	5	(1.8)
Pneumonitis	1	(0.4)
Pulmonary embolism	2	(0.7)
Skin and subcutaneous tissue disorders	**3**	**(1.1)**
Haemorrhage subcutaneous	1	(0.4)
Rash generalised	1	(0.4)
Rash maculo-papular	1	(0.4)
Vascular disorders	**5**	**(1.8)**

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付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
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001 試験パート B2+D（APaT 集団）（続き）

	Ipi-naïve 2 mg/kg Q3W		Ipi-naïve 10 mg/kg Q3W		Ipi-exposed 2 mg/kg Q3W		Ipi-exposed 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)	n	(%)
Vascular disorders	**1**	**(2.0)**	**2**	**(3.8)**	**0**	**(0.0)**	**2**	**(2.4)**
Embolism	0	(0.0)	1	(1.9)	0	(0.0)	1	(1.2)
Haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Peripheral ischaemia	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Vena cava thrombosis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)

付録 2.7.4-20 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Total	
	n	(%)
Vascular disorders	**5**	**(1.8)**
Embolism	2	(0.7)
Haemorrhage	1	(0.4)
Peripheral ischaemia	1	(0.4)
Vena cava thrombosis	1	(0.4)

Every patient is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
MedDRA preferred terms 'Malignant neoplasm progression' not related to the drug is excluded.
(Database Cutoff Date: [redacted]

Data Source: [資料5.3.5.2.1.2: P001V02]

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