Appendix 2.7.4: 3
Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	33	(84.6)	35	(87.5)	38	(92.7)	35	(87.5)	35	(92.1)	176	(88.9)
Patients With No Adverse Experience	6	(15.4)	5	(12.5)	3	(7.3)	5	(12.5)	3	(7.9)	22	(11.1)
Blood And Lymphatic System Disorders	1	(2.6)	0	(0.0)	0	(0.0)	3	(7.5)	2	(5.3)	6	(3.0)
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Lymph Node Pain	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Lymphadenopathy	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.0)	1	(2.6)	3	(1.5)
Neutropenia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Cardiac Disorders	1	(2.6)	1	(2.5)	2	(4.9)	1	(2.5)	0	(0.0)	5	(2.5)
Atrioventricular Block First Degree	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Bradycardia	1	(2.6)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)
Bundle Branch Block Right	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Palpitations	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Ear And Labyrinth Disorders	0	(0.0)	2	(5.0)	1	(2.4)	2	(5.0)	0	(0.0)	5	(2.5)
Cerumen Impaction	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Hypoacusis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Tympanic Membrane Hyperaemia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Vertigo	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Eye Disorders	3	(7.7)	3	(7.5)	3	(7.3)	2	(5.0)	5	(13.2)	16	(8.1)
Altered Visual Depth Perception	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Blepharitis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye Disorders	3	(7.7)	3	(7.5)	3	(7.3)	2	(5.0)	5	(13.2)	16	(8.1)
Conjunctivitis	1	(2.6)	1	(2.5)	2	(4.9)	0	(0.0)	3	(7.9)	7	(3.5)
Eye Pain	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Eye Pruritus	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Eyelid Cyst	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Myopia	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Retinal Vein Occlusion	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Visual Disturbance	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Gastrointestinal Disorders	20	(51.3)	18	(45.0)	19	(46.3)	21	(52.5)	21	(55.3)	99	(50.0)
Abdominal Discomfort	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Distension	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Abdominal Hernia	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Mass	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Pain	1	(2.6)	2	(5.0)	3	(7.3)	2	(5.0)	3	(7.9)	11	(5.6)
Abdominal Pain Lower	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Pain Upper	1	(2.6)	0	(0.0)	2	(4.9)	2	(5.0)	0	(0.0)	5	(2.5)
Abdominal Tenderness	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Anal Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Anal Fissure	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Anal Ulcer	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Aphthous Stomatitis	0	(0.0)	2	(5.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Barrett's Oesophagus	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	20	(51.3)	18	(45.0)	19	(46.3)	21	(52.5)	21	(55.3)	99	(50.0)
Cheilitis	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Constipation	0	(0.0)	0	(0.0)	3	(7.3)	1	(2.5)	1	(2.6)	5	(2.5)
Dental Caries	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Diarrhoea	8	(20.5)	7	(17.5)	5	(12.2)	11	(27.5)	8	(21.1)	39	(19.7)
Dry Mouth	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)
Dyspepsia	0	(0.0)	1	(2.5)	2	(4.9)	2	(5.0)	0	(0.0)	5	(2.5)
Enterocolitis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Flatulence	2	(5.1)	2	(5.0)	4	(9.8)	2	(5.0)	1	(2.6)	11	(5.6)
Food Poisoning	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	1	(2.6)	3	(1.5)
Frequent Bowel Movements	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastritis	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	3	(1.5)
Gastrointestinal Disorder	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastrooesophageal Reflux Disease	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Gingival Bleeding	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Gingivitis	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Haemorrhoidal Haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Haemorrhoids	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Hiatus Hernia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Lip Pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Mouth Ulceration	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Mucous Stools	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	20	(51.3)	18	(45.0)	19	(46.3)	21	(52.5)	21	(55.3)	99	(50.0)
Nausea	7	(17.9)	7	(17.5)	8	(19.5)	9	(22.5)	6	(15.8)	37	(18.7)
Oesophagitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Oral Lichen Planus	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Rectal Haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Salivary Duct Inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Salivary Hypersecretion	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Sensitivity Of Teeth	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Stomach Discomfort	0	(0.0)	2	(5.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Stomatitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Toothache	1	(2.6)	2	(5.0)	1	(2.4)	2	(5.0)	0	(0.0)	6	(3.0)
Vomiting	2	(5.1)	4	(10.0)	2	(4.9)	1	(2.5)	7	(18.4)	16	(8.1)
General Disorders And Administration Site Conditions	8	(20.5)	9	(22.5)	12	(29.3)	6	(15.0)	10	(26.3)	45	(22.7)
Chest Discomfort	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Chest Pain	1	(2.6)	1	(2.5)	1	(2.4)	2	(5.0)	0	(0.0)	5	(2.5)
Face Oedema	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Fatigue	1	(2.6)	1	(2.5)	6	(14.6)	1	(2.5)	2	(5.3)	11	(5.6)
Feeling Abnormal	2	(5.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Feeling Drunk	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Influenza Like Illness	0	(0.0)	2	(5.0)	1	(2.4)	1	(2.5)	2	(5.3)	6	(3.0)
Irritability	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	8	(20.5)	9	(22.5)	12	(29.3)	6	(15.0)	10	(26.3)	45	(22.7)
Malaise	0	(0.0)	2	(5.0)	2	(4.9)	0	(0.0)	3	(7.9)	7	(3.5)
Oedema Peripheral	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	1	(2.6)	3	(1.5)
Pain	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Pyrexia	5	(12.8)	2	(5.0)	1	(2.4)	0	(0.0)	1	(2.6)	9	(4.5)
Thirst	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Ulcer	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatobiliary Disorders	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Bile Duct Obstruction	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Cholelithiasis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatic Steatosis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Immune System Disorders	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Seasonal Allergy	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Infections And Infestations	22	(56.4)	28	(70.0)	28	(68.3)	25	(62.5)	27	(71.1)	130	(65.7)
Abdominal Abscess	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abscess Limb	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Abscess Neck	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abscess Of Eyelid	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Acarodermatitis	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	1	(2.6)	3	(1.5)
Amoebic Colitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Amoebic Dysentery	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	22	(56.4)	28	(70.0)	28	(68.3)	25	(62.5)	27	(71.1)	130	(65.7)
Anal Abscess	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Anogenital Warts	0	(0.0)	2	(5.0)	0	(0.0)	1	(2.5)	2	(5.3)	5	(2.5)
Body Tinea	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	2	(5.3)	4	(2.0)
Bronchitis	2	(5.1)	2	(5.0)	3	(7.3)	3	(7.5)	2	(5.3)	12	(6.1)
Bronchitis Acute	1	(2.6)	2	(5.0)	0	(0.0)	2	(5.0)	1	(2.6)	6	(3.0)
Bronchitis Viral	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Campylobacter Gastroenteritis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Candidiasis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Cellulitis	0	(0.0)	3	(7.5)	1	(2.4)	0	(0.0)	1	(2.6)	5	(2.5)
Chlamydial Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Chronic Sinusitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Cystitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Dengue Fever	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Ear Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Ecthyma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Folliculitis	1	(2.6)	0	(0.0)	1	(2.4)	1	(2.5)	1	(2.6)	4	(2.0)
Fungal Infection	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Furuncle	1	(2.6)	1	(2.5)	0	(0.0)	2	(5.0)	0	(0.0)	4	(2.0)
Gastritis Viral	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastroenteritis	1	(2.6)	1	(2.5)	1	(2.4)	0	(0.0)	2	(5.3)	5	(2.5)
Gastrointestinal Protozoal Infection	0	(0.0)	1	(2.5)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	22	(56.4)	28	(70.0)	28	(68.3)	25	(62.5)	27	(71.1)	130	(65.7)
Giardiasis	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Gonorrhoea	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Helicobacter Infection	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatitis C	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Herpes Simplex	4	(10.3)	5	(12.5)	0	(0.0)	2	(5.0)	1	(2.6)	12	(6.1)
Herpes Simplex Visceral	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Herpes Zoster	3	(7.7)	0	(0.0)	1	(2.4)	1	(2.5)	4	(10.5)	9	(4.5)
Impetigo	0	(0.0)	2	(5.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Infected Skin Ulcer	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Infection Parasitic	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Influenza	0	(0.0)	2	(5.0)	0	(0.0)	1	(2.5)	2	(5.3)	5	(2.5)
Lice Infestation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Localised Infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.3)	2	(1.0)
Nasopharyngitis	5	(12.8)	4	(10.0)	6	(14.6)	4	(10.0)	6	(15.8)	25	(12.6)
Onychomycosis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	2	(5.3)	3	(1.5)
Otitis Externa	0	(0.0)	0	(0.0)	0	(0.0)	3	(7.5)	0	(0.0)	3	(1.5)
Otitis Media	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Paronychia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Periorbital Cellulitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Pertussis	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Pharyngitis	3	(7.7)	3	(7.5)	3	(7.3)	2	(5.0)	2	(5.3)	13	(6.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	22	(56.4)	28	(70.0)	28	(68.3)	25	(62.5)	27	(71.1)	130	(65.7)
Pneumonia	1	(2.6)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Pneumonia Streptococcal	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Pyelonephritis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Rash Pustular	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Respiratory Tract Infection	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Rhinitis	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	1	(2.6)	3	(1.5)
Sinusitis	2	(5.1)	3	(7.5)	1	(2.4)	3	(7.5)	2	(5.3)	11	(5.6)
Skin Infection	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Staphylococcal Infection	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Streptococcal Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Subcutaneous Abscess	2	(5.1)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Syphilis	1	(2.6)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Tinea Cruris	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tinea Infection	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Tinea Pedis	1	(2.6)	2	(5.0)	1	(2.4)	0	(0.0)	1	(2.6)	5	(2.5)
Tinea Versicolour	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Tonsillitis	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Tooth Abscess	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Tooth Infection	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Upper Respiratory Tract Infection	5	(12.8)	7	(17.5)	10	(24.4)	4	(10.0)	7	(18.4)	33	(16.7)
Urethritis	2	(5.1)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	4	(2.0)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	22	(56.4)	28	(70.0)	28	(68.3)	25	(62.5)	27	(71.1)	130	(65.7)
Urethritis Chlamydial	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Urinary Tract Infection	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Vaginal Candidiasis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Vaginal Infection	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Viral Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Viral Pharyngitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Viral Upper Respiratory Tract Infection	0	(0.0)	0	(0.0)	1	(2.4)	2	(5.0)	0	(0.0)	3	(1.5)
Injury, Poisoning And Procedural Complications	6	(15.4)	3	(7.5)	6	(14.6)	4	(10.0)	2	(5.3)	21	(10.6)
Burns Second Degree	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Contusion	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)
Device Malfunction	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Excoriation	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Face Injury	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Fall	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Hand Fracture	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Heat Stroke	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Intentional Overdose	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Joint Dislocation	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Joint Sprain	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Limb Injury	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Lower Limb Fracture	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)

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	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, Poisoning And Procedural Complications	6	(15.4)	3	(7.5)	6	(14.6)	4	(10.0)	2	(5.3)	21	(10.6)
Muscle Strain	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Nail Avulsion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Open Wound	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Post-Traumatic Pain	1	(2.6)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Procedural Pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Radiation Skin Injury	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Seroma	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Thermal Burn	1	(2.6)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Tooth Fracture	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Traumatic Haematoma	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Investigations	1	(2.6)	1	(2.5)	2	(4.9)	0	(0.0)	1	(2.6)	5	(2.5)
Weight Decreased	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Weight Increased	0	(0.0)	1	(2.5)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)
Metabolism And Nutrition Disorders	1	(2.6)	3	(7.5)	2	(4.9)	3	(7.5)	1	(2.6)	10	(5.1)
Anorexia	1	(2.6)	1	(2.5)	0	(0.0)	2	(5.0)	1	(2.6)	5	(2.5)
Decreased Appetite	0	(0.0)	0	(0.0)	2	(4.9)	1	(2.5)	0	(0.0)	3	(1.5)
Fat Intolerance	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Gout	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hypernatraemia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Lipomatosis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	6	(15.4)	9	(22.5)	7	(17.1)	9	(22.5)	4	(10.5)	35	(17.7)
Arthralgia	3	(7.7)	2	(5.0)	2	(4.9)	3	(7.5)	1	(2.6)	11	(5.6)
Arthropathy	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Back Pain	3	(7.7)	1	(2.5)	3	(7.3)	2	(5.0)	0	(0.0)	9	(4.5)
Costochondritis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Intervertebral Disc Degeneration	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Joint Swelling	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Limb Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Muscle Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Muscle Spasms	2	(5.1)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	3	(1.5)
Muscle Swelling	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Musculoskeletal Chest Pain	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Musculoskeletal Pain	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Musculoskeletal Stiffness	1	(2.6)	0	(0.0)	0	(0.0)	2	(5.0)	0	(0.0)	3	(1.5)
Myalgia	0	(0.0)	1	(2.5)	1	(2.4)	2	(5.0)	2	(5.3)	6	(3.0)
Neck Pain	1	(2.6)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Osteoarthritis	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Pain In Extremity	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	3	(7.9)	5	(2.5)
Pain In Jaw	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Synovitis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tendonitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	6	(15.4)	9	(22.5)	7	(17.1)	9	(22.5)	4	(10.5)	35	(17.7)
Tenosynovitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Torticollis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	0	(0.0)	2	(5.0)	3	(7.3)	3	(7.5)	2	(5.3)	10	(5.1)
Buccal Cavity Papilloma	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Kaposi's Sarcoma	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Keratoacanthoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Papilloma	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Skin Papilloma	0	(0.0)	1	(2.5)	1	(2.4)	2	(5.0)	1	(2.6)	5	(2.5)
Squamous Cell Carcinoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Uterine Leiomyoma	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nervous System Disorders	17	(43.6)	16	(40.0)	13	(31.7)	15	(37.5)	22	(57.9)	83	(41.9)
Amnesia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Balance Disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Cervicobrachial Syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Disturbance In Attention	0	(0.0)	1	(2.5)	0	(0.0)	2	(5.0)	2	(5.3)	5	(2.5)
Dizziness	7	(17.9)	7	(17.5)	1	(2.4)	3	(7.5)	12	(31.6)	30	(15.2)
Headache	6	(15.4)	6	(15.0)	10	(24.4)	6	(15.0)	13	(34.2)	41	(20.7)
Hypoaesthesia	0	(0.0)	3	(7.5)	0	(0.0)	1	(2.5)	0	(0.0)	4	(2.0)
Hypogeusia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous System Disorders	17	(43.6)	16	(40.0)	13	(31.7)	15	(37.5)	22	(57.9)	83	(41.9)
Lethargy	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	2	(5.3)	4	(2.0)
Memory Impairment	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Migraine	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	1	(2.6)	3	(1.5)
Neuropathy Peripheral	2	(5.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Paraesthesia	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Poor Quality Sleep	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Post Herpetic Neuralgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Presyncope	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Sciatica	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Sinus Headache	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Somnolence	3	(7.7)	0	(0.0)	0	(0.0)	2	(5.0)	1	(2.6)	6	(3.0)
Syncope	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Tension Headache	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Psychiatric Disorders	9	(23.1)	11	(27.5)	11	(26.8)	11	(27.5)	15	(39.5)	57	(28.8)
Abnormal Dreams	1	(2.6)	4	(10.0)	4	(9.8)	2	(5.0)	8	(21.1)	19	(9.6)
Adjustment Disorder With Depressed Mood	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Alcoholism	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Anxiety	0	(0.0)	0	(0.0)	2	(4.9)	3	(7.5)	3	(7.9)	8	(4.0)
Anxiety Disorder	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Bruxism	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Depressed Mood	0	(0.0)	1	(2.5)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric Disorders	9	(23.1)	11	(27.5)	11	(26.8)	11	(27.5)	15	(39.5)	57	(28.8)
Depression	3	(7.7)	1	(2.5)	3	(7.3)	4	(10.0)	3	(7.9)	14	(7.1)
Disorientation	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Insomnia	6	(15.4)	6	(15.0)	5	(12.2)	4	(10.0)	4	(10.5)	25	(12.6)
Libido Decreased	0	(0.0)	1	(2.5)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)
Loss Of Libido	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nightmare	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(10.5)	4	(2.0)
Sleep Disorder	2	(5.1)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.5)
Suicidal Ideation	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Renal And Urinary Disorders	2	(5.1)	2	(5.0)	2	(4.9)	2	(5.0)	2	(5.3)	10	(5.1)
Bladder Mass	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Calculus Urinary	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Dysuria	2	(5.1)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	4	(2.0)
Nephrolithiasis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	1	(2.6)	2	(1.0)
Nocturia	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Renal Colic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Renal Impairment	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Reproductive System And Breast Disorders	1	(2.6)	2	(5.0)	1	(2.4)	3	(7.5)	1	(2.6)	8	(4.0)
Cervical Dysplasia	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Erectile Dysfunction	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Genital Burning Sensation	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Genital Lesion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Reproductive System And Breast Disorders	1	(2.6)	2	(5.0)	1	(2.4)	3	(7.5)	1	(2.6)	8	(4.0)
Genital Rash	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Penile Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Peyronie's Disease	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Prostatism	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Prostatitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Respiratory, Thoracic And Mediastinal Disorders	1	(2.6)	6	(15.0)	5	(12.2)	8	(20.0)	5	(13.2)	25	(12.6)
Asthma	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)
Cough	0	(0.0)	3	(7.5)	1	(2.4)	2	(5.0)	1	(2.6)	7	(3.5)
Dyspnoea	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Nasal Congestion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	1	(2.6)	2	(1.0)
Pharyngolaryngeal Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Pharyngolaryngeal Pain	0	(0.0)	0	(0.0)	2	(4.9)	1	(2.5)	1	(2.6)	4	(2.0)
Pleural Effusion	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Productive Cough	0	(0.0)	1	(2.5)	0	(0.0)	2	(5.0)	0	(0.0)	3	(1.5)
Rhinitis Allergic	1	(2.6)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)
Sinus Congestion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Tonsillar Hypertrophy	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Vocal Cord Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Wheezing	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Skin And Subcutaneous Tissue Disorders	11	(28.2)	14	(35.0)	13	(31.7)	11	(27.5)	12	(31.6)	61	(30.8)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	11	(28.2)	14	(35.0)	13	(31.7)	11	(27.5)	12	(31.6)	61	(30.8)
Acne	0	(0.0)	1	(2.5)	2	(4.9)	1	(2.5)	0	(0.0)	4	(2.0)
Alopecia	2	(5.1)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Blister	2	(5.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Dermal Cyst	0	(0.0)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	2	(1.0)
Dermatitis	2	(5.1)	1	(2.5)	0	(0.0)	1	(2.5)	2	(5.3)	6	(3.0)
Dermatitis Allergic	0	(0.0)	0	(0.0)	2	(4.9)	0	(0.0)	1	(2.6)	3	(1.5)
Dermatitis Atopic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Dermatitis Contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Dry Skin	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Dyshidrosis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Ecchymosis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Eczema	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Eczema Asteatotic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Eosinophilic Pustular Folliculitis	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Erythema	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Erythema Multiforme	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Hyperkeratosis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Ingrowing Nail	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Ingrown Hair	0	(0.0)	0	(0.0)	1	(2.4)	2	(5.0)	1	(2.6)	4	(2.0)
Keloid Scar	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Lichen Planus	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	11	(28.2)	14	(35.0)	13	(31.7)	11	(27.5)	12	(31.6)	61	(30.8)
Night Sweats	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Penile Ulceration	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Photosensitivity Reaction	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Pruritus	3	(7.7)	4	(10.0)	2	(4.9)	2	(5.0)	2	(5.3)	13	(6.6)
Pruritus Generalised	1	(2.6)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Psoriasis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Rash	0	(0.0)	2	(5.0)	2	(4.9)	1	(2.5)	1	(2.6)	6	(3.0)
Rash Erythematous	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Rash Macular	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)
Rash Maculo-Papular	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Rash Papular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(7.9)	3	(1.5)
Rash Vesicular	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Seborrhoea	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Seborrhoeic Dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.0)	2	(5.3)	4	(2.0)
Skin Exfoliation	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Skin Hyperpigmentation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Skin Lesion	1	(2.6)	2	(5.0)	0	(0.0)	1	(2.5)	2	(5.3)	6	(3.0)
Skin Swelling	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Urticaria	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	2	(5.3)	3	(1.5)
Vascular Disorders	1	(2.6)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)
Haematoma	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular Disorders	1	(2.6)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)
Hypertension	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.
Adverse experience terms are from MedDRA Version 9.1

[Ref. 5.3.5.1: P005-Define, P018-Define, P019-Define]

Appendix 2.7.4: 4
Number (%) of Patients With Specific Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	31	(79.5)	35	(87.5)	36	(87.8)	35	(87.5)	34	(89.5)	171	(86.4)
Patients With No Adverse Experience	8	(20.5)	5	(12.5)	5	(12.2)	5	(12.5)	4	(10.5)	27	(13.6)
Blood And Lymphatic System Disorders	1	(2.6)	0	(0.0)	0	(0.0)	3	(7.5)	2	(5.3)	6	(3.0)
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Lymph Node Pain	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Lymphadenopathy	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.0)	1	(2.6)	3	(1.5)
Neutropenia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Cardiac Disorders	1	(2.6)	1	(2.5)	2	(4.9)	1	(2.5)	0	(0.0)	5	(2.5)
Atrioventricular Block First Degree	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Bradycardia	1	(2.6)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)
Bundle Branch Block Right	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Palpitations	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Ear And Labyrinth Disorders	0	(0.0)	2	(5.0)	1	(2.4)	2	(5.0)	0	(0.0)	5	(2.5)
Cerumen Impaction	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Hypoacusis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tinnitus	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Tympanic Membrane Hyperaemia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Vertigo	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Eye Disorders	1	(2.6)	3	(7.5)	3	(7.3)	2	(5.0)	3	(7.9)	12	(6.1)
Altered Visual Depth Perception	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Blepharitis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Eye Disorders	1	(2.6)	3	(7.5)	3	(7.3)	2	(5.0)	3	(7.9)	12	(6.1)
Conjunctivitis	0	(0.0)	1	(2.5)	2	(4.9)	0	(0.0)	1	(2.6)	4	(2.0)
Eye Pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Eye Pruritus	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Eyelid Cyst	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Myopia	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Retinal Vein Occlusion	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Visual Disturbance	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Gastrointestinal Disorders	19	(48.7)	18	(45.0)	19	(46.3)	18	(45.0)	19	(50.0)	93	(47.0)
Abdominal Discomfort	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Distension	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Mass	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Pain	1	(2.6)	2	(5.0)	2	(4.9)	1	(2.5)	3	(7.9)	9	(4.5)
Abdominal Pain Lower	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Pain Upper	1	(2.6)	0	(0.0)	2	(4.9)	2	(5.0)	0	(0.0)	5	(2.5)
Abdominal Tenderness	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Anal Fissure	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Anal Ulcer	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Aphthous Stomatitis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Constipation	0	(0.0)	0	(0.0)	3	(7.3)	1	(2.5)	1	(2.6)	5	(2.5)
Diarrhoea	8	(20.5)	7	(17.5)	5	(12.2)	10	(25.0)	8	(21.1)	38	(19.2)
Dry Mouth	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)

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	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	19	(48.7)	18	(45.0)	19	(46.3)	18	(45.0)	19	(50.0)	93	(47.0)
Dyspepsia	0	(0.0)	1	(2.5)	1	(2.4)	2	(5.0)	0	(0.0)	4	(2.0)
Enterocolitis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Flatulence	2	(5.1)	2	(5.0)	4	(9.8)	2	(5.0)	1	(2.6)	11	(5.6)
Food Poisoning	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	1	(2.6)	3	(1.5)
Frequent Bowel Movements	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastritis	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	3	(1.5)
Gastrointestinal Disorder	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastrooesophageal Reflux Disease	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Gingival Bleeding	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Gingivitis	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Haemorrhoidal Haemorrhage	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Haemorrhoids	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Lip Pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Mouth Ulceration	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Mucous Stools	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Nausea	6	(15.4)	7	(17.5)	8	(19.5)	8	(20.0)	6	(15.8)	35	(17.7)
Oral Lichen Planus	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Pruritus Ani	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Salivary Hypersecretion	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Sensitivity Of Teeth	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Stomach Discomfort	0	(0.0)	2	(5.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)

Number (%) of Patients With Specific Clinical Adverse Experiences
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	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	19	(48.7)	18	(45.0)	19	(46.3)	18	(45.0)	19	(50.0)	93	(47.0)
Toothache	1	(2.6)	2	(5.0)	1	(2.4)	1	(2.5)	0	(0.0)	5	(2.5)
Vomiting	2	(5.1)	4	(10.0)	2	(4.9)	0	(0.0)	6	(15.8)	14	(7.1)
General Disorders And Administration Site Conditions	8	(20.5)	7	(17.5)	9	(22.0)	6	(15.0)	8	(21.1)	38	(19.2)
Chest Discomfort	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Chest Pain	0	(0.0)	1	(2.5)	0	(0.0)	2	(5.0)	0	(0.0)	3	(1.5)
Fatigue	1	(2.6)	1	(2.5)	6	(14.6)	1	(2.5)	2	(5.3)	11	(5.6)
Feeling Abnormal	2	(5.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Feeling Drunk	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Influenza Like Illness	0	(0.0)	1	(2.5)	1	(2.4)	1	(2.5)	1	(2.6)	4	(2.0)
Irritability	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Malaise	0	(0.0)	1	(2.5)	2	(4.9)	0	(0.0)	3	(7.9)	6	(3.0)
Oedema Peripheral	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Pain	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Pyrexia	4	(10.3)	2	(5.0)	0	(0.0)	0	(0.0)	0	(0.0)	6	(3.0)
Thirst	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatobiliary Disorders	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Bile Duct Obstruction	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Cholelithiasis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatic Steatosis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Immune System Disorders	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Immune System Disorders	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Seasonal Allergy	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Infections And Infestations	19	(48.7)	26	(65.0)	26	(63.4)	24	(60.0)	24	(63.2)	119	(60.1)
Abscess Neck	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abscess Of Eyelid	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Acarodermatitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	1	(2.6)	2	(1.0)
Amoebic Colitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Amoebic Dysentery	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Anal Abscess	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Body Tinea	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	2	(5.3)	3	(1.5)
Bronchitis	1	(2.6)	0	(0.0)	2	(4.9)	2	(5.0)	1	(2.6)	6	(3.0)
Bronchitis Acute	1	(2.6)	1	(2.5)	0	(0.0)	2	(5.0)	1	(2.6)	5	(2.5)
Campylobacter Gastroenteritis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Candidiasis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Cellulitis	0	(0.0)	3	(7.5)	1	(2.4)	0	(0.0)	1	(2.6)	5	(2.5)
Chlamydial Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Chronic Sinusitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Condyloma Acuminatum	0	(0.0)	2	(5.0)	0	(0.0)	1	(2.5)	1	(2.6)	4	(2.0)
Dengue Fever	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Ear Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Ecthyma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Folliculitis	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	1	(2.6)	3	(1.5)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	19	(48.7)	26	(65.0)	26	(63.4)	24	(60.0)	24	(63.2)	119	(60.1)
Furuncle	1	(2.6)	1	(2.5)	0	(0.0)	2	(5.0)	0	(0.0)	4	(2.0)
Gastritis Viral	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gastroenteritis	1	(2.6)	1	(2.5)	1	(2.4)	0	(0.0)	1	(2.6)	4	(2.0)
Gastrointestinal Protozoal Infection	0	(0.0)	1	(2.5)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)
Giardiasis	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Gonorrhoea	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Helicobacter Infection	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Herpes Simplex	4	(10.3)	3	(7.5)	0	(0.0)	2	(5.0)	1	(2.6)	10	(5.1)
Herpes Simplex Visceral	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Herpes Zoster	3	(7.7)	0	(0.0)	1	(2.4)	1	(2.5)	4	(10.5)	9	(4.5)
Impetigo	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Infected Skin Ulcer	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Influenza	0	(0.0)	3	(7.5)	0	(0.0)	1	(2.5)	2	(5.3)	6	(3.0)
Lice Infestation	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Localised Infection	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Nasopharyngitis	3	(7.7)	4	(10.0)	6	(14.6)	4	(10.0)	5	(13.2)	22	(11.1)
Onychomycosis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Otitis Externa	0	(0.0)	0	(0.0)	0	(0.0)	3	(7.5)	0	(0.0)	3	(1.5)
Paronychia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Periorbital Cellulitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Pertussis	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	19	(48.7)	26	(65.0)	26	(63.4)	24	(60.0)	24	(63.2)	119	(60.1)
Pharyngitis	3	(7.7)	2	(5.0)	2	(4.9)	2	(5.0)	1	(2.6)	10	(5.1)
Pneumonia	1	(2.6)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Pneumonia Streptococcal	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Pyelonephritis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Rash Pustular	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Rhinitis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Scrotal Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Sialoadenitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Sinusitis	0	(0.0)	2	(5.0)	1	(2.4)	3	(7.5)	1	(2.6)	7	(3.5)
Skin Infection	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Staphylococcal Infection	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Streptococcal Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Subcutaneous Abscess	2	(5.1)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Syphilis	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Tinea Cruris	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tinea Infection	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Tinea Pedis	1	(2.6)	2	(5.0)	1	(2.4)	0	(0.0)	1	(2.6)	5	(2.5)
Tonsillitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Tooth Infection	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Upper Respiratory Tract Infection	5	(12.8)	7	(17.5)	10	(24.4)	5	(12.5)	7	(18.4)	34	(17.2)
Urethritis	2	(5.1)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.5)

Number (%) of Patients With Specific Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	19	(48.7)	26	(65.0)	26	(63.4)	24	(60.0)	24	(63.2)	119	(60.1)
Urethritis Chlamydial	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Urinary Tract Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Vaginal Candidiasis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Vaginal Infection	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Viral Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Viral Pharyngitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Viral Upper Respiratory Tract Infection	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.0)	0	(0.0)	2	(1.0)
Injury, Poisoning And Procedural Complications	5	(12.8)	3	(7.5)	4	(9.8)	4	(10.0)	1	(2.6)	17	(8.6)
Burns Second Degree	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Contusion	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Device Malfunction	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Excoriation	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hand Fracture	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Heat Stroke	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Intentional Overdose	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Joint Sprain	1	(2.6)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Limb Crushing Injury	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Limb Injury	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Lower Limb Fracture	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Nail Avulsion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Open Wound	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences
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(Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, Poisoning And Procedural Complications	5	(12.8)	3	(7.5)	4	(9.8)	4	(10.0)	1	(2.6)	17	(8.6)
Post-Traumatic Pain	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Procedural Pain	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Seroma	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Thermal Burn	1	(2.6)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Tooth Fracture	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Investigations	1	(2.6)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Weight Decreased	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Weight Increased	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Metabolism And Nutrition Disorders	1	(2.6)	2	(5.0)	1	(2.4)	2	(5.0)	1	(2.6)	7	(3.5)
Anorexia	1	(2.6)	1	(2.5)	0	(0.0)	2	(5.0)	1	(2.6)	5	(2.5)
Decreased Appetite	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Fat Intolerance	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Hypernatraemia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Musculoskeletal And Connective Tissue Disorders	6	(15.4)	7	(17.5)	6	(14.6)	8	(20.0)	4	(10.5)	31	(15.7)
Arthralgia	3	(7.7)	2	(5.0)	2	(4.9)	3	(7.5)	1	(2.6)	11	(5.6)
Back Pain	3	(7.7)	0	(0.0)	0	(0.0)	2	(5.0)	0	(0.0)	5	(2.5)
Costochondritis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Joint Swelling	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Limb Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Muscle Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)

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	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	6	(15.4)	7	(17.5)	6	(14.6)	8	(20.0)	4	(10.5)	31	(15.7)
Muscle Swelling	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Musculoskeletal Chest Pain	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Musculoskeletal Stiffness	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Myalgia	0	(0.0)	1	(2.5)	0	(0.0)	2	(5.0)	1	(2.6)	4	(2.0)
Neck Pain	1	(2.6)	2	(5.0)	1	(2.4)	0	(0.0)	0	(0.0)	4	(2.0)
Osteoarthritis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Pain In Extremity	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	3	(7.9)	5	(2.5)
Pain In Jaw	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Scoliosis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Synovitis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Tendonitis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Tenosynovitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Torticollis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	0	(0.0)	2	(5.0)	4	(9.8)	3	(7.5)	2	(5.3)	11	(5.6)
Buccal Cavity Papilloma	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Kaposi's Sarcoma	0	(0.0)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	2	(1.0)
Keratoacanthoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Papilloma	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Skin Papilloma	0	(0.0)	1	(2.5)	1	(2.4)	2	(5.0)	1	(2.6)	5	(2.5)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	0	(0.0)	2	(5.0)	4	(9.8)	3	(7.5)	2	(5.3)	11	(5.6)
Squamous Cell Carcinoma	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Uterine Leiomyoma	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nervous System Disorders	15	(38.5)	15	(37.5)	12	(29.3)	13	(32.5)	22	(57.9)	77	(38.9)
Amnesia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Balance Disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Cervicobrachial Syndrome	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Disturbance In Attention	0	(0.0)	1	(2.5)	0	(0.0)	2	(5.0)	2	(5.3)	5	(2.5)
Dizziness	7	(17.9)	8	(20.0)	1	(2.4)	3	(7.5)	13	(34.2)	32	(16.2)
Headache	6	(15.4)	5	(12.5)	10	(24.4)	5	(12.5)	12	(31.6)	38	(19.2)
Hypoaesthesia	0	(0.0)	3	(7.5)	0	(0.0)	1	(2.5)	0	(0.0)	4	(2.0)
Hypogeusia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Lethargy	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	2	(5.3)	4	(2.0)
Memory Impairment	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Migraine	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Neuropathy Peripheral	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Paraesthesia	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Poor Quality Sleep	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Post Herpetic Neuralgia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Sciatica	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Sinus Headache	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous System Disorders	15	(38.5)	15	(37.5)	12	(29.3)	13	(32.5)	22	(57.9)	77	(38.9)
Somnolence	2	(5.1)	0	(0.0)	0	(0.0)	2	(5.0)	1	(2.6)	5	(2.5)
Syncope	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Psychiatric Disorders	8	(20.5)	9	(22.5)	10	(24.4)	8	(20.0)	13	(34.2)	48	(24.2)
Abnormal Dreams	1	(2.6)	4	(10.0)	4	(9.8)	2	(5.0)	8	(21.1)	19	(9.6)
Adjustment Disorder With Depressed Mood	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Anxiety	0	(0.0)	0	(0.0)	2	(4.9)	1	(2.5)	2	(5.3)	5	(2.5)
Anxiety Disorder	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Bruxism	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Depressed Mood	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Depression	3	(7.7)	0	(0.0)	3	(7.3)	3	(7.5)	2	(5.3)	11	(5.6)
Disorientation	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Insomnia	5	(12.8)	5	(12.5)	4	(9.8)	3	(7.5)	4	(10.5)	21	(10.6)
Libido Decreased	0	(0.0)	1	(2.5)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)
Loss Of Libido	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nightmare	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(10.5)	4	(2.0)
Sleep Disorder	2	(5.1)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.5)
Suicidal Ideation	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Renal And Urinary Disorders	1	(2.6)	2	(5.0)	1	(2.4)	2	(5.0)	2	(5.3)	8	(4.0)
Bladder Mass	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Calculus Urinary	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Dysuria	1	(2.6)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	3	(1.5)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Renal And Urinary Disorders	1	(2.6)	2	(5.0)	1	(2.4)	2	(5.0)	2	(5.3)	8	(4.0)
Nephrolithiasis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	1	(2.6)	2	(1.0)
Nocturia	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Renal Colic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Reproductive System And Breast Disorders	1	(2.6)	1	(2.5)	1	(2.4)	2	(5.0)	1	(2.6)	6	(3.0)
Cervical Dysplasia	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Erectile Dysfunction	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Genital Burning Sensation	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Penile Pain	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Peyronie's Disease	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Prostatism	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Prostatitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Respiratory, Thoracic And Mediastinal Disorders	1	(2.6)	5	(12.5)	4	(9.8)	7	(17.5)	5	(13.2)	22	(11.1)
Asthma	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)
Cough	0	(0.0)	2	(5.0)	0	(0.0)	2	(5.0)	1	(2.6)	5	(2.5)
Dyspnoea	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Nasal Congestion	0	(0.0)	0	(0.0)	1	(2.4)	2	(5.0)	1	(2.6)	4	(2.0)
Pharyngolaryngeal Pain	0	(0.0)	0	(0.0)	2	(4.9)	1	(2.5)	1	(2.6)	4	(2.0)
Pleural Effusion	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Productive Cough	0	(0.0)	1	(2.5)	0	(0.0)	2	(5.0)	0	(0.0)	3	(1.5)
Rhinitis Allergic	1	(2.6)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)

Number (%) of Patients With Specific Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, Thoracic And Mediastinal Disorders	1	(2.6)	5	(12.5)	4	(9.8)	7	(17.5)	5	(13.2)	22	(11.1)
Sinus Congestion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Tonsillar Hypertrophy	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Wheezing	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Skin And Subcutaneous Tissue Disorders	9	(23.1)	13	(32.5)	9	(22.0)	11	(27.5)	12	(31.6)	54	(27.3)
Acne	0	(0.0)	1	(2.5)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)
Alopecia	2	(5.1)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Blister	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Dermal Cyst	0	(0.0)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	2	(1.0)
Dermatitis	1	(2.6)	2	(5.0)	0	(0.0)	1	(2.5)	2	(5.3)	6	(3.0)
Dermatitis Allergic	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)
Dermatitis Atopic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Dermatitis Contact	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Dry Skin	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Dyshidrosis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Ecchymosis	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Eczema	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Eczema Asteatotic	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Erythema	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Erythema Multiforme	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Hyperkeratosis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	9	(23.1)	13	(32.5)	9	(22.0)	11	(27.5)	12	(31.6)	54	(27.3)
Ingrowing Nail	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Ingrown Hair	0	(0.0)	0	(0.0)	1	(2.4)	2	(5.0)	1	(2.6)	4	(2.0)
Lichen Planus	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Penile Ulceration	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Photosensitivity Reaction	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Pruritus	3	(7.7)	4	(10.0)	2	(4.9)	2	(5.0)	2	(5.3)	13	(6.6)
Pruritus Generalised	1	(2.6)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Psoriasis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Rash	0	(0.0)	2	(5.0)	2	(4.9)	1	(2.5)	1	(2.6)	6	(3.0)
Rash Erythematous	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Rash Papular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	3	(7.9)	3	(1.5)
Rash Vesicular	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	1	(2.6)	2	(1.0)
Seborrhoea	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Seborrhoeic Dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.0)	1	(2.6)	3	(1.5)
Skin Exfoliation	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Skin Hyperpigmentation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Skin Lesion	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.3)	3	(1.5)
Skin Ulcer	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	9	(23.1)	13	(32.5)	9	(22.0)	11	(27.5)	12	(31.6)	54	(27.3)
Urticaria	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Vascular Disorders	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Hypertension	1	(2.6)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.
Adverse experience terms are from MedDRA Version 9.0

[Ref. 5.3.5.1: P004]

Appendix 2.7.4: 5

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	18	(46.2)	21	(52.5)	20	(48.8)	20	(50.0)	27	(71.1)	106	(53.5)
Patients With No Adverse Experience	21	(53.8)	19	(47.5)	21	(51.2)	20	(50.0)	11	(28.9)	92	(46.5)
Blood And Lymphatic System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Cardiac Disorders	1	(2.6)	0	(0.0)	2	(4.9)	1	(2.5)	0	(0.0)	4	(2.0)
Atrioventricular Block First Degree	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Bradycardia	1	(2.6)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)
Bundle Branch Block Right	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Palpitations	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Eye Disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.3)	2	(1.0)
Altered Visual Depth Perception	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Visual Disturbance	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Gastrointestinal Disorders	8	(20.5)	13	(32.5)	11	(26.8)	14	(35.0)	12	(31.6)	58	(29.3)
Abdominal Distension	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Abdominal Pain	0	(0.0)	2	(5.0)	2	(4.9)	0	(0.0)	0	(0.0)	4	(2.0)
Abdominal Pain Lower	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Pain Upper	1	(2.6)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)
Constipation	0	(0.0)	0	(0.0)	3	(7.3)	1	(2.5)	1	(2.6)	5	(2.5)
Diarrhoea	2	(5.1)	1	(2.5)	3	(7.3)	5	(12.5)	4	(10.5)	15	(7.6)
Dry Mouth	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)
Dyspepsia	0	(0.0)	1	(2.5)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	8	(20.5)	13	(32.5)	11	(26.8)	14	(35.0)	12	(31.6)	58	(29.3)
Flatulence	2	(5.1)	2	(5.0)	3	(7.3)	2	(5.0)	1	(2.6)	10	(5.1)
Frequent Bowel Movements	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gingival Bleeding	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Nausea	3	(7.7)	6	(15.0)	4	(9.8)	7	(17.5)	5	(13.2)	25	(12.6)
Oral Lichen Planus	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Salivary Hypersecretion	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Vomiting	0	(0.0)	1	(2.5)	2	(4.9)	1	(2.5)	3	(7.9)	7	(3.5)
General Disorders And Administration Site Conditions	2	(5.1)	3	(7.5)	5	(12.2)	2	(5.0)	6	(15.8)	18	(9.1)
Fatigue	1	(2.6)	1	(2.5)	4	(9.8)	1	(2.5)	2	(5.3)	9	(4.5)
Feeling Abnormal	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Feeling Drunk	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Irritability	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Malaise	0	(0.0)	0	(0.0)	2	(4.9)	0	(0.0)	3	(7.9)	5	(2.5)
Pyrexia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Thirst	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatobiliary Disorders	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatic Steatosis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Infections And Infestations	0	(0.0)	0	(0.0)	2	(4.9)	1	(2.5)	0	(0.0)	3	(1.5)
Folliculitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Gastrointestinal Protozoal Infection	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	0	(0.0)	0	(0.0)	2	(4.9)	1	(2.5)	0	(0.0)	3	(1.5)
Herpes Zoster	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Metabolism And Nutrition Disorders	1	(2.6)	2	(5.0)	1	(2.4)	2	(5.0)	0	(0.0)	6	(3.0)
Anorexia	1	(2.6)	1	(2.5)	0	(0.0)	2	(5.0)	0	(0.0)	4	(2.0)
Decreased Appetite	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Fat Intolerance	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Lipomatosis	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Musculoskeletal And Connective Tissue Disorders	1	(2.6)	3	(7.5)	0	(0.0)	1	(2.5)	1	(2.6)	6	(3.0)
Arthralgia	1	(2.6)	1	(2.5)	0	(0.0)	1	(2.5)	1	(2.6)	4	(2.0)
Joint Swelling	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Muscle Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Myalgia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Nervous System Disorders	9	(23.1)	11	(27.5)	8	(19.5)	8	(20.0)	17	(44.7)	53	(26.8)
Balance Disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Disturbance In Attention	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	2	(5.3)	3	(1.5)
Dizziness	6	(15.4)	5	(12.5)	1	(2.4)	2	(5.0)	11	(28.9)	25	(12.6)
Headache	1	(2.6)	4	(10.0)	6	(14.6)	3	(7.5)	9	(23.7)	23	(11.6)
Hypoaesthesia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Hypogeusia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Lethargy	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	2	(5.3)	4	(2.0)
Memory Impairment	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous System Disorders	9	(23.1)	11	(27.5)	8	(19.5)	8	(20.0)	17	(44.7)	53	(26.8)
Neuropathy Peripheral	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Paraesthesia	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Poor Quality Sleep	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Somnolence	2	(5.1)	0	(0.0)	0	(0.0)	2	(5.0)	1	(2.6)	5	(2.5)
Psychiatric Disorders	5	(12.8)	8	(20.0)	4	(9.8)	4	(10.0)	12	(31.6)	33	(16.7)
Abnormal Dreams	1	(2.6)	4	(10.0)	4	(9.8)	1	(2.5)	7	(18.4)	17	(8.6)
Anxiety	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	2	(5.3)	4	(2.0)
Depression	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Disorientation	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Insomnia	3	(7.7)	4	(10.0)	2	(4.9)	2	(5.0)	4	(10.5)	15	(7.6)
Libido Decreased	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Loss Of Libido	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nightmare	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(10.5)	4	(2.0)
Sleep Disorder	2	(5.1)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.5)
Renal And Urinary Disorders	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Renal Impairment	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Reproductive System And Breast Disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Erectile Dysfunction	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Skin And Subcutaneous Tissue Disorders	5	(12.8)	5	(12.5)	2	(4.9)	3	(7.5)	3	(7.9)	18	(9.1)
Alopecia	2	(5.1)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Lichen Planus	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	5	(12.8)	5	(12.5)	2	(4.9)	3	(7.5)	3	(7.9)	18	(9.1)
Pruritus	2	(5.1)	3	(7.5)	0	(0.0)	2	(5.0)	0	(0.0)	7	(3.5)
Pruritus Generalised	1	(2.6)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)
Rash	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Rash Macular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Rash Papular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Urticaria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and efavirenz were administered with tenofovir and lamivudine.
Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P004-Define]

Appendix 2.7.4: 6
Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004 - Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Drug-Related Adverse Experiences	18	(46.2)	20	(50.0)	19	(46.3)	19	(47.5)	27	(71.1)	103	(52.0)
Patients With No Drug-Related Adverse Experience	21	(53.8)	20	(50.0)	22	(53.7)	21	(52.5)	11	(28.9)	95	(48.0)
Blood And Lymphatic System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Cardiac Disorders	1	(2.6)	0	(0.0)	2	(4.9)	1	(2.5)	0	(0.0)	4	(2.0)
Atrioventricular Block First Degree	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Bradycardia	1	(2.6)	0	(0.0)	2	(4.9)	0	(0.0)	0	(0.0)	3	(1.5)
Bundle Branch Block Right	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Palpitations	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Eye Disorders	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	2	(5.3)	2	(1.0)
Altered Visual Depth Perception	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Visual Disturbance	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Gastrointestinal Disorders	7	(17.9)	12	(30.0)	10	(24.4)	13	(32.5)	12	(31.6)	54	(27.3)
Abdominal Distension	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Pain	0	(0.0)	2	(5.0)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Abdominal Pain Lower	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Abdominal Pain Upper	1	(2.6)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	3	(1.5)
Constipation	0	(0.0)	0	(0.0)	3	(7.3)	1	(2.5)	1	(2.6)	5	(2.5)
Diarrhoea	1	(2.6)	1	(2.5)	3	(7.3)	5	(12.5)	4	(10.5)	14	(7.1)
Dry Mouth	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	1	(2.6)	2	(1.0)
Dyspepsia	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004 - Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	7	(17.9)	12	(30.0)	10	(24.4)	13	(32.5)	12	(31.6)	54	(27.3)
Flatulence	2	(5.1)	2	(5.0)	3	(7.3)	2	(5.0)	1	(2.6)	10	(5.1)
Frequent Bowel Movements	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Gingival Bleeding	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Nausea	3	(7.7)	5	(12.5)	4	(9.8)	6	(15.0)	5	(13.2)	23	(11.6)
Oral Lichen Planus	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Salivary Hypersecretion	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Vomiting	0	(0.0)	1	(2.5)	2	(4.9)	0	(0.0)	3	(7.9)	6	(3.0)
General Disorders And Administration Site Conditions	2	(5.1)	3	(7.5)	5	(12.2)	2	(5.0)	6	(15.8)	18	(9.1)
Fatigue	1	(2.6)	1	(2.5)	4	(9.8)	1	(2.5)	2	(5.3)	9	(4.5)
Feeling Abnormal	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Feeling Drunk	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Irritability	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Malaise	0	(0.0)	0	(0.0)	2	(4.9)	0	(0.0)	3	(7.9)	5	(2.5)
Pyrexia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Thirst	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatobiliary Disorders	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Hepatic Steatosis	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Infections And Infestations	0	(0.0)	0	(0.0)	2	(4.9)	1	(2.5)	0	(0.0)	3	(1.5)
Folliculitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Gastrointestinal Protozoal Infection	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004 - Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	0	(0.0)	0	(0.0)	2	(4.9)	1	(2.5)	0	(0.0)	3	(1.5)
Herpes Zoster	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Metabolism And Nutrition Disorders	1	(2.6)	1	(2.5)	1	(2.4)	2	(5.0)	0	(0.0)	5	(2.5)
Anorexia	1	(2.6)	1	(2.5)	0	(0.0)	2	(5.0)	0	(0.0)	4	(2.0)
Decreased Appetite	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Fat Intolerance	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Musculoskeletal And Connective Tissue Disorders	1	(2.6)	3	(7.5)	0	(0.0)	1	(2.5)	1	(2.6)	6	(3.0)
Arthralgia	1	(2.6)	1	(2.5)	0	(0.0)	1	(2.5)	1	(2.6)	4	(2.0)
Joint Swelling	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Muscle Fatigue	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Myalgia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Nervous System Disorders	9	(23.1)	11	(27.5)	8	(19.5)	8	(20.0)	17	(44.7)	53	(26.8)
Balance Disorder	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Disturbance In Attention	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	2	(5.3)	3	(1.5)
Dizziness	6	(15.4)	5	(12.5)	1	(2.4)	2	(5.0)	11	(28.9)	25	(12.6)
Headache	1	(2.6)	4	(10.0)	6	(14.6)	3	(7.5)	9	(23.7)	23	(11.6)
Hypoaesthesia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Hypogeusia	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Lethargy	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	2	(5.3)	4	(2.0)
Memory Impairment	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Neuropathy Peripheral	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004 - Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous System Disorders	9	(23.1)	11	(27.5)	8	(19.5)	8	(20.0)	17	(44.7)	53	(26.8)
Paraesthesia	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Poor Quality Sleep	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Somnolence	2	(5.1)	0	(0.0)	0	(0.0)	2	(5.0)	1	(2.6)	5	(2.5)
Psychiatric Disorders	4	(10.3)	8	(20.0)	4	(9.8)	4	(10.0)	12	(31.6)	32	(16.2)
Abnormal Dreams	1	(2.6)	4	(10.0)	4	(9.8)	1	(2.5)	7	(18.4)	17	(8.6)
Anxiety	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	2	(5.3)	4	(2.0)
Depression	0	(0.0)	0	(0.0)	1	(2.4)	1	(2.5)	0	(0.0)	2	(1.0)
Disorientation	0	(0.0)	1	(2.5)	0	(0.0)	0	(0.0)	1	(2.6)	2	(1.0)
Insomnia	2	(5.1)	4	(10.0)	2	(4.9)	2	(5.0)	4	(10.5)	14	(7.1)
Libido Decreased	0	(0.0)	1	(2.5)	1	(2.4)	0	(0.0)	0	(0.0)	2	(1.0)
Loss Of Libido	1	(2.6)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.5)
Nightmare	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	4	(10.5)	4	(2.0)
Sleep Disorder	2	(5.1)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	3	(1.5)
Reproductive System And Breast Disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Erectile Dysfunction	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.5)	0	(0.0)	1	(0.5)
Skin And Subcutaneous Tissue Disorders	5	(12.8)	5	(12.5)	2	(4.9)	3	(7.5)	3	(7.9)	18	(9.1)
Alopecia	2	(5.1)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	3	(1.5)
Erythema	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Lichen Planus	0	(0.0)	0	(0.0)	1	(2.4)	0	(0.0)	0	(0.0)	1	(0.5)
Pruritus	2	(5.1)	3	(7.5)	0	(0.0)	2	(5.0)	0	(0.0)	7	(3.5)
Pruritus Generalised	1	(2.6)	1	(2.5)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.0)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 004 - Cohorts I and II Combined; Combination Therapy Phase, Weeks 0 to 48) - *Original Application*

	MK-0518 100 mg b.i.d. (N = 39)		MK-0518 200 mg b.i.d. (N = 40)		MK-0518 400 mg b.i.d. (N = 41)		MK-0518 600 mg b.i.d. (N = 40)		Efavirenz 600 mg q.d. (N = 38)		Total (N = 198)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	5	(12.8)	5	(12.5)	2	(4.9)	3	(7.5)	3	(7.9)	18	(9.1)
Rash	0	(0.0)	1	(2.5)	0	(0.0)	1	(2.5)	0	(0.0)	2	(1.0)
Rash Papular	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)
Urticaria	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.6)	1	(0.5)

Although a patient may have had two or more drug-related clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Adverse experience terms are from MedDRA Version 9.0.

[Ref. 5.3.5.1: P004]

Appendix 2.7.4: 7

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N=39)		MK-0518 200 mg b.i.d. (N=40)		MK-0518 400 mg b.i.d. (N=41)		MK-0518 600 mg b.i.d. (N=40)		Efavirenz 600 mg q.d. (N=38)		Total (N=198)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Patients with one or more adverse experiences	8/39	(20.5)	8/40	(20.0)	11/41	(26.8)	6/40	(15.0)	10/38	(26.3)	43/198	(21.7)
Patients with no adverse experiences	31/39	(79.5)	32/40	(80.0)	30/41	(73.2)	34/40	(85.0)	28/38	(73.7)	155/198	(78.3)
Blood Chemistry Test	**8/39**	**(20.5)**	**8/40**	**(20.0)**	**11/41**	**(26.8)**	**3/40**	**(7.5)**	**8/38**	(21.1)	38/198	(19.2)
Alanine aminotransferase increased	1/39	(2.6)	5/40	(12.5)	1/41	(2.4)	2/40	(5.0)	4/38	(10.5)	13/198	(6.6)
Alkaline phosphatase increased	1/39	(2.6)	4/40	(10.0)	0/41	(0.0)	0/40	(0.0)	1/38	(2.6)	6/198	(3.0)
Aspartate aminotransferase increased	2/39	(5.1)	5/40	(12.5)	2/41	(4.9)	1/40	(2.5)	5/38	(13.2)	15/198	(7.6)
Blood amylase decreased	0/39	(0.0)	1/40	(2.5)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Blood amylase increased	2/39	(5.1)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	2/198	(1.0)
Blood bicarbonate decreased	1/39	(2.6)	0/40	(0.0)	1/41	(2.4)	0/40	(0.0)	0/38	(0.0)	2/198	(1.0)
Blood bilirubin increased	1/39	(2.6)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Blood bilirubin indirect increased	1/39	(2.6)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Blood creatinine increased	1/39	(2.6)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	1/38	(2.6)	2/198	(1.0)
Blood pancreatic amylase increased	0/2	(0.0)	0/5	(0.0)	2/2	(100.0)	0/2	(0.0)	0/3	(0.0)	2/14	(14.3)
Blood phosphorus decreased	1/39	(2.6)	0/40	(0.0)	1/41	(2.4)	0/40	(0.0)	0/38	(0.0)	2/198	(1.0)
Blood potassium decreased	0/39	(0.0)	1/40	(2.5)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Blood sodium increased	0/39	(0.0)	0/40	(0.0)	1/41	(2.4)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Blood triglycerides increased	1/39	(2.6)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	2/38	(5.3)	3/198	(1.5)
Creatine phosphokinase increased	2/39	(5.1)	3/40	(7.5)	2/41	(4.9)	0/40	(0.0)	2/38	(5.3)	9/198	(4.5)
Fasting blood glucose increased	0/39	(0.0)	0/40	(0.0)	1/41	(2.4)	1/40	(2.5)	1/38	(2.6)	3/198	(1.5)
Gamma-glutamyltransferase increased	0/†		1/1	(100.0)	0/†		0/†		0/1	(0.0)	1/2	(50.0)
Lipase increased	1/39	(2.6)	0/40	(0.0)	2/41	(4.9)	0/40	(0.0)	0/38	(0.0)	3/198	(1.5)

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N=39)		MK-0518 200 mg b.i.d. (N=40)		MK-0518 400 mg b.i.d. (N=41)		MK-0518 600 mg b.i.d. (N=40)		Efavirenz 600 mg q.d. (N=38)		Total (N=198)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Blood Chemistry Test	**8/39**	**(20.5)**	**8/40**	**(20.0)**	**11/41**	**(26.8)**	**3/40**	**(7.5)**	**8/38**	(21.1)	38/198	(19.2)
Low density lipoprotein increased	0/39	(0.0)	1/40	(2.5)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Protein total increased	0/39	(0.0)	1/40	(2.5)	2/41	(4.9)	0/40	(0.0)	0/38	(0.0)	3/198	(1.5)
Hematology Laboratory Test	**0/39**	**(0.0)**	**1/40**	**(2.5)**	**0/41**	**(0.0)**	**2/40**	**(5.0)**	**2/38**	(5.3)	5/198	(2.5)
Absolute neutrophil count decreased	0/39	(0.0)	1/40	(2.5)	0/41	(0.0)	0/40	(0.0)	1/38	(2.6)	2/198	(1.0)
Haemoglobin decreased	0/39	(0.0)	0/40	(0.0)	0/41	(0.0)	1/40	(2.5)	0/38	(0.0)	1/198	(0.5)
Platelet count decreased	0/39	(0.0)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	1/38	(2.6)	1/198	(0.5)
White blood cell count decreased	0/39	(0.0)	0/40	(0.0)	0/41	(0.0)	1/40	(2.5)	0/38	(0.0)	1/198	(0.5)
Urinalysis Test	**0/39**	**(0.0)**	**1/40**	**(2.5)**	**0/41**	**(0.0)**	**1/40**	**(2.5)**	**1/38**	(2.6)	3/198	(1.5)
Red blood cells urine positive	0/39	(0.0)	1/40	(2.5)	0/41	(0.0)	1/40	(2.5)	1/38	(2.6)	3/198	(1.5)

† indicates there was no associated laboratory test or there were no patients for whom the laboratory test was recorded postbaseline.

n/m = number of patients with laboratory adverse experiences / number of patients for whom the laboratory test was recorded postbaseline.

Although a patient may have had two or more laboratory adverse experiences, the patient is counted only once in a category. The same patient may appear in different categories.

Note: MK-0518 and efavirenz were administered with tenofovir and lamivudine.
Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P004-Define]

Appendix 2.7.4: 8

Number (%) of Patients With Specific Drug-Related Laboratory Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N=39)		MK-0518 200 mg b.i.d. (N=40)		MK-0518 400 mg b.i.d. (N=41)		MK-0518 600 mg b.i.d. (N=40)		Efavirenz 600 mg q.d. (N=38)		Total (N=198)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Patients with one or more adverse experiences	3/39	(7.7)	7/40	(17.5)	4/41	(9.8)	3/40	(7.5)	3/38	(7.9)	20/198	(10.1)
Patients with no adverse experiences	36/39	(92.3)	33/40	(82.5)	37/41	(90.2)	37/40	(92.5)	35/38	(92.1)	178/198	(89.9)
Blood Chemistry Test	**3/39**	**(7.7)**	**7/40**	**(17.5)**	**4/41**	**(9.8)**	**2/40**	**(5.0)**	**2/38**	(5.3)	18/198	(9.1)
Alanine aminotransferase increased	0/39	(0.0)	4/40	(10.0)	0/41	(0.0)	2/40	(5.0)	2/38	(5.3)	8/198	(4.0)
Alkaline phosphatase increased	0/39	(0.0)	3/40	(7.5)	0/41	(0.0)	0/40	(0.0)	1/38	(2.6)	4/198	(2.0)
Aspartate aminotransferase increased	1/39	(2.6)	4/40	(10.0)	1/41	(2.4)	1/40	(2.5)	2/38	(5.3)	9/198	(4.5)
Blood bicarbonate decreased	1/39	(2.6)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Blood creatinine increased	1/39	(2.6)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Blood pancreatic amylase increased	0/2	(0.0)	0/5	(0.0)	1/2	(50.0)	0/2	(0.0)	0/3	(0.0)	1/14	(7.1)
Blood phosphorus decreased	0/39	(0.0)	0/40	(0.0)	1/41	(2.4)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Blood triglycerides increased	0/39	(0.0)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	1/38	(2.6)	1/198	(0.5)
Creatine phosphokinase increased	1/39	(2.6)	1/40	(2.5)	1/41	(2.4)	0/40	(0.0)	0/38	(0.0)	3/198	(1.5)
Fasting blood glucose increased	0/39	(0.0)	0/40	(0.0)	1/41	(2.4)	0/40	(0.0)	1/38	(2.6)	2/198	(1.0)
Gamma-glutamyltransferase increased	0/†		1/1	(100.0)	0/†		0/†		0/1	(0.0)	1/2	(50.0)
Low density lipoprotein increased	0/39	(0.0)	1/40	(2.5)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)
Protein total increased	0/39	(0.0)	1/40	(2.5)	0/41	(0.0)	0/40	(0.0)	0/38	(0.0)	1/198	(0.5)

Number (%) of Patients With Specific Drug-Related Laboratory Adverse Experiences—Overall: Related to Blinded Therapy With MK-0518 or Efavirenz or Open-Label Therapy With Lamivudine or Tenofovir (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 004: Cohorts I and II Combined; Combination Therapy Phase, Entire Study Period) - *Cumulative Data*

	MK-0518 100 mg b.i.d. (N=39)		MK-0518 200 mg b.i.d. (N=40)		MK-0518 400 mg b.i.d. (N=41)		MK-0518 600 mg b.i.d. (N=40)		Efavirenz 600 mg q.d. (N=38)		Total (N=198)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Hematology Laboratory Test	**0/39**	**(0.0)**	**1/40**	**(2.5)**	**0/41**	**(0.0)**	**1/40**	**(2.5)**	**2/38**	(5.3)	4/198	(2.0)
Absolute neutrophil count decreased	0/39	(0.0)	1/40	(2.5)	0/41	(0.0)	0/40	(0.0)	1/38	(2.6)	2/198	(1.0)
Haemoglobin decreased	0/39	(0.0)	0/40	(0.0)	0/41	(0.0)	1/40	(2.5)	0/38	(0.0)	1/198	(0.5)
Platelet count decreased	0/39	(0.0)	0/40	(0.0)	0/41	(0.0)	0/40	(0.0)	1/38	(2.6)	1/198	(0.5)

† indicates there was no associated laboratory test or there were no patients for whom the laboratory test was recorded postbaseline.

n/m = number of patients with laboratory adverse experiences / number of patients for whom the laboratory test was recorded postbaseline.

Although a patient may have had two or more laboratory adverse experiences, the patient is counted only once in a category. The same patient may appear in different categories.

Note: MK-0518 and efavirenz were administered with tenofovir and lamivudine.
Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P004-Define]

Appendix 2.7.4: 9
Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	40	(93.0)	38	(84.4)	43	(95.6)	38	(84.4)	159	(89.3)
Patients With No Adverse Experience	3	(7.0)	7	(15.6)	2	(4.4)	7	(15.6)	19	(10.7)
Blood And Lymphatic System Disorders	4	(9.3)	4	(8.9)	7	(15.6)	4	(8.9)	19	(10.7)
Anaemia	0	(0.0)	0	(0.0)	1	(2.2)	2	(4.4)	3	(1.7)
Iron Deficiency Anaemia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Lymphadenopathy	3	(7.0)	3	(6.7)	5	(11.1)	2	(4.4)	13	(7.3)
Spleen Disorder	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Splenomegaly	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Thrombocytopenia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cardiac Disorders	0	(0.0)	2	(4.4)	4	(8.9)	4	(8.9)	10	(5.6)
Acute Myocardial Infarction	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Angina Pectoris	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Arrhythmia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Atrioventricular Block First Degree	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Bradycardia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cardio-Respiratory Arrest	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cardiovascular Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Coronary Artery Disease	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Mitral Valve Incompetence	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Palpitations	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Tachycardia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Congenital, Familial And Genetic Disorders	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Porphyria	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Ear And Labyrinth Disorders	2	(4.7)	1	(2.2)	0	(0.0)	0	(0.0)	3	(1.7)
Cerumen Impaction	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Tinnitus	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vertigo	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Endocrine Disorders	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Adrenal Insufficiency	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Eye Disorders	2	(4.7)	5	(11.1)	6	(13.3)	1	(2.2)	14	(7.9)
Blindness Transient	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Cataract	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Chorioretinal Disorder	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Conjunctivitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Eye Oedema	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Eyelids Pruritus	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Ocular Icterus	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Papilloedema	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Photopsia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Vision Blurred	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Visual Acuity Reduced	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Visual Disturbance	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gastrointestinal Disorders	21	(48.8)	20	(44.4)	26	(57.8)	22	(48.9)	89	(50.0)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	21	(48.8)	20	(44.4)	26	(57.8)	22	(48.9)	89	(50.0)
Abdominal Discomfort	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Abdominal Distension	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Abdominal Pain	3	(7.0)	4	(8.9)	3	(6.7)	3	(6.7)	13	(7.3)
Abdominal Pain Upper	1	(2.3)	2	(4.4)	2	(4.4)	0	(0.0)	5	(2.8)
Abdominal Tenderness	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Anal Fissure	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Anogenital Dysplasia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Aphthous Stomatitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Ascites	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Cheilitis	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Constipation	3	(7.0)	1	(2.2)	1	(2.2)	1	(2.2)	6	(3.4)
Dental Caries	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Diarrhoea	13	(30.2)	4	(8.9)	5	(11.1)	8	(17.8)	30	(16.9)
Dry Mouth	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Dyspepsia	1	(2.3)	0	(0.0)	1	(2.2)	3	(6.7)	5	(2.8)
Dysphagia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Epigastric Discomfort	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Flatulence	1	(2.3)	1	(2.2)	1	(2.2)	2	(4.4)	5	(2.8)
Gastric Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Gastric Varices	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Gastritis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	21	(48.8)	20	(44.4)	26	(57.8)	22	(48.9)	89	(50.0)
Gastrointestinal Disorder	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Gastrooesophageal Reflux Disease	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gingival Pain	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Glossitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Glossodynia	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Haemorrhoids	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Hiatus Hernia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hypoaesthesia Oral	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Inguinal Hernia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Irritable Bowel Syndrome	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Leukoplakia Oral	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Mouth Ulceration	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Nausea	5	(11.6)	5	(11.1)	9	(20.0)	10	(22.2)	29	(16.3)
Odynophagia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Oral Mucosal Blistering	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Oral Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Oral Soft Tissue Disorder	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pancreatitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Periodontitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Pruritus Ani	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Rectal Haemorrhage	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	21	(48.8)	20	(44.4)	26	(57.8)	22	(48.9)	89	(50.0)
Rectal Tenesmus	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Stomach Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tongue Ulceration	1	(2.3)	1	(2.2)	2	(4.4)	0	(0.0)	4	(2.2)
Toothache	0	(0.0)	1	(2.2)	0	(0.0)	2	(4.4)	3	(1.7)
Vomiting	4	(9.3)	3	(6.7)	3	(6.7)	2	(4.4)	12	(6.7)
General Disorders And Administration Site Conditions	15	(34.9)	13	(28.9)	16	(35.6)	10	(22.2)	54	(30.3)
Application Site Dryness	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Asthenia	3	(7.0)	1	(2.2)	1	(2.2)	3	(6.7)	8	(4.5)
Chest Discomfort	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)
Chest Pain	0	(0.0)	1	(2.2)	0	(0.0)	1	(2.2)	2	(1.1)
Chills	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Drug Intolerance	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Fat Tissue Increased	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Fatigue	5	(11.6)	3	(6.7)	4	(8.9)	4	(8.9)	16	(9.0)
Feeling Hot	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Injection Site Bruising	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Erythema	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Injection Site Induration	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Injection Site Inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Injection Site Nodule	1	(2.3)	1	(2.2)	0	(0.0)	1	(2.2)	3	(1.7)
Injection Site Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	15	(34.9)	13	(28.9)	16	(35.6)	10	(22.2)	54	(30.3)
Injection Site Reaction	2	(4.7)	5	(11.1)	4	(8.9)	3	(6.7)	14	(7.9)
Irritability	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Local Swelling	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Malaise	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Nodule	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)
Oedema Peripheral	2	(4.7)	2	(4.4)	1	(2.2)	0	(0.0)	5	(2.8)
Pain	3	(7.0)	0	(0.0)	0	(0.0)	2	(4.4)	5	(2.8)
Pitting Oedema	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pyrexia	3	(7.0)	1	(2.2)	3	(6.7)	1	(2.2)	8	(4.5)
Sensation Of Pressure	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tenderness	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Xerosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hepatobiliary Disorders	3	(7.0)	4	(8.9)	3	(6.7)	0	(0.0)	10	(5.6)
Cholecystitis	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Hepatitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hepatomegaly	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hepatosplenomegaly	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Hyperbilirubinaemia	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Jaundice	0	(0.0)	3	(6.7)	0	(0.0)	0	(0.0)	3	(1.7)
Portal Hypertensive Gastropathy	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Immune System Disorders	2	(4.7)	0	(0.0)	1	(2.2)	2	(4.4)	5	(2.8)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Immune System Disorders	2	(4.7)	0	(0.0)	1	(2.2)	2	(4.4)	5	(2.8)
Drug Hypersensitivity	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Hypersensitivity	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Jarisch-Herxheimer Reaction	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Infections And Infestations	28	(65.1)	23	(51.1)	27	(60.0)	23	(51.1)	101	(56.7)
Acarodermatitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Acute Sinusitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Anogenital Warts	1	(2.3)	3	(6.7)	3	(6.7)	1	(2.2)	8	(4.5)
Bronchitis	2	(4.7)	2	(4.4)	6	(13.3)	5	(11.1)	15	(8.4)
Bronchitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Candidiasis	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Cellulitis	1	(2.3)	1	(2.2)	2	(4.4)	0	(0.0)	4	(2.2)
Chronic Sinusitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Conjunctivitis Infective	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Dermatophytosis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Disseminated Tuberculosis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Ear Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Erysipelas	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Folliculitis	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Fungal Infection	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Fungal Skin Infection	1	(2.3)	0	(0.0)	0	(0.0)	2	(4.4)	3	(1.7)
Furuncle	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	28	(65.1)	23	(51.1)	27	(60.0)	23	(51.1)	101	(56.7)
Gastroenteritis	1	(2.3)	2	(4.4)	0	(0.0)	0	(0.0)	3	(1.7)
Gastroenteritis Viral	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Genital Infection Fungal	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Giardiasis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Herpes Simplex	6	(14.0)	3	(6.7)	1	(2.2)	2	(4.4)	12	(6.7)
Herpes Virus Infection	2	(4.7)	1	(2.2)	0	(0.0)	0	(0.0)	3	(1.7)
Herpes Zoster	1	(2.3)	1	(2.2)	2	(4.4)	1	(2.2)	5	(2.8)
Influenza	6	(14.0)	5	(11.1)	4	(8.9)	1	(2.2)	16	(9.0)
Injection Site Cellulitis	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Leishmaniasis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Lower Respiratory Tract Infection	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Nasopharyngitis	5	(11.6)	3	(6.7)	5	(11.1)	2	(4.4)	15	(8.4)
Oesophageal Candidiasis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Onychomycosis	0	(0.0)	0	(0.0)	3	(6.7)	2	(4.4)	5	(2.8)
Oral Candidiasis	2	(4.7)	1	(2.2)	2	(4.4)	0	(0.0)	5	(2.8)
Oral Hairy Leukoplakia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Osteomyelitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Otitis Externa	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Papilloma Viral Infection	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Paronychia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pharyngitis	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	28	(65.1)	23	(51.1)	27	(60.0)	23	(51.1)	101	(56.7)
Pharyngotonsillitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Pneumocystis Jiroveci Pneumonia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pneumonia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pneumonia Bacterial	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pneumonia Herpes Viral	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pseudofolliculitis Barbae	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pyoderma	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Respiratory Tract Infection	2	(4.7)	1	(2.2)	1	(2.2)	1	(2.2)	5	(2.8)
Rhinitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Secondary Syphilis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Sepsis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Sinusitis	1	(2.3)	5	(11.1)	0	(0.0)	1	(2.2)	7	(3.9)
Sinusitis Bacterial	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Skin Infection	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Splenic Abscess	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Staphylococcal Abscess	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Staphylococcal Infection	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)
Syphilis	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Tinea Cruris	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Tinea Pedis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Tooth Abscess	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	28	(65.1)	23	(51.1)	27	(60.0)	23	(51.1)	101	(56.7)
Tooth Infection	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Tracheitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Tracheobronchitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tuberculosis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Upper Respiratory Tract Infection	2	(4.7)	3	(6.7)	3	(6.7)	3	(6.7)	11	(6.2)
Urinary Tract Infection	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vaginal Candidiasis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vaginitis Bacterial	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Varicella	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Viral Diarrhoea	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Viral Infection	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Viral Upper Respiratory Tract Infection	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Injury, Poisoning And Procedural Complications	4	(9.3)	5	(11.1)	7	(15.6)	1	(2.2)	17	(9.6)
Arthropod Bite	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Clavicle Fracture	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Contusion	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Drug Toxicity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Excoriation	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Fall	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Fibula Fracture	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hand Fracture	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, Poisoning And Procedural Complications	4	(9.3)	5	(11.1)	7	(15.6)	1	(2.2)	17	(9.6)
Head Injury	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Joint Injury	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Laceration	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Limb Injury	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Poisoning	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Post Procedural Haematoma	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Radius Fracture	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Road Traffic Accident	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Skin Laceration	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Tibia Fracture	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Investigations	4	(9.3)	1	(2.2)	0	(0.0)	2	(4.4)	7	(3.9)
Blood Pressure Diastolic Increased	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Blood Pressure Increased	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Blood Testosterone Decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Electrocardiogram Change	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Spleen Palpable	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Weight Decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Weight Increased	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Metabolism And Nutrition Disorders	4	(9.3)	8	(17.8)	4	(8.9)	3	(6.7)	19	(10.7)
Anorexia	1	(2.3)	2	(4.4)	0	(0.0)	1	(2.2)	4	(2.2)
Central Obesity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	4	(9.3)	8	(17.8)	4	(8.9)	3	(6.7)	19	(10.7)
Decreased Appetite	1	(2.3)	0	(0.0)	2	(4.4)	1	(2.2)	4	(2.2)
Diabetes Mellitus	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dyslipidaemia	2	(4.7)	2	(4.4)	1	(2.2)	0	(0.0)	5	(2.8)
Facial Wasting	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Hypercholesterolaemia	0	(0.0)	2	(4.4)	0	(0.0)	1	(2.2)	3	(1.7)
Hyperglycaemia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hypophosphataemia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Metabolic Acidosis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Obesity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Musculoskeletal And Connective Tissue Disorders	12	(27.9)	8	(17.8)	7	(15.6)	6	(13.3)	33	(18.5)
Arthralgia	1	(2.3)	3	(6.7)	0	(0.0)	2	(4.4)	6	(3.4)
Arthritis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Back Pain	4	(9.3)	1	(2.2)	1	(2.2)	0	(0.0)	6	(3.4)
Bone Pain	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Bursitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Groin Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Muscle Atrophy	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Muscle Hypertrophy	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Muscle Spasms	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Muscular Weakness	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Musculoskeletal Chest Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	12	(27.9)	8	(17.8)	7	(15.6)	6	(13.3)	33	(18.5)
Musculoskeletal Pain	1	(2.3)	0	(0.0)	2	(4.4)	0	(0.0)	3	(1.7)
Myalgia	2	(4.7)	2	(4.4)	1	(2.2)	0	(0.0)	5	(2.8)
Myositis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Neck Pain	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pain In Extremity	1	(2.3)	2	(4.4)	2	(4.4)	1	(2.2)	6	(3.4)
Plantar Fasciitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Synovial Cyst	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Tendonitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tenosynovitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	0	(0.0)	3	(6.7)	0	(0.0)	1	(2.2)	4	(2.2)
Skin Papilloma	0	(0.0)	3	(6.7)	0	(0.0)	1	(2.2)	4	(2.2)
Nervous System Disorders	11	(25.6)	9	(20.0)	13	(28.9)	11	(24.4)	44	(24.7)
Amnesia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Aphonia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Carotid Artery Atheroma	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Disturbance In Attention	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Dizziness	1	(2.3)	3	(6.7)	1	(2.2)	0	(0.0)	5	(2.8)
Dysgeusia	2	(4.7)	1	(2.2)	1	(2.2)	1	(2.2)	5	(2.8)
Dysphasia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Facial Palsy	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous System Disorders	11	(25.6)	9	(20.0)	13	(28.9)	11	(24.4)	44	(24.7)
Headache	5	(11.6)	4	(8.9)	7	(15.6)	5	(11.1)	21	(11.8)
Hyperreflexia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hypoaesthesia	1	(2.3)	0	(0.0)	1	(2.2)	1	(2.2)	3	(1.7)
Hyporeflexia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Lacunar Infarction	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Loss Of Consciousness	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Memory Impairment	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Neuropathy	1	(2.3)	0	(0.0)	1	(2.2)	2	(4.4)	4	(2.2)
Neuropathy Peripheral	0	(0.0)	1	(2.2)	2	(4.4)	1	(2.2)	4	(2.2)
Paraesthesia	0	(0.0)	2	(4.4)	1	(2.2)	0	(0.0)	3	(1.7)
Sciatica	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Sinus Headache	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Somnolence	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Syncope	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Psychiatric Disorders	9	(20.9)	5	(11.1)	5	(11.1)	5	(11.1)	24	(13.5)
Anxiety	0	(0.0)	2	(4.4)	1	(2.2)	1	(2.2)	4	(2.2)
Confusional State	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Depression	3	(7.0)	1	(2.2)	3	(6.7)	1	(2.2)	8	(4.5)
Insomnia	4	(9.3)	3	(6.7)	3	(6.7)	2	(4.4)	12	(6.7)
Mood Altered	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric Disorders	9	(20.9)	5	(11.1)	5	(11.1)	5	(11.1)	24	(13.5)
Nervousness	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Sleep Disorder	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Stress	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Renal And Urinary Disorders	1	(2.3)	3	(6.7)	5	(11.1)	2	(4.4)	11	(6.2)
Dysuria	0	(0.0)	1	(2.2)	1	(2.2)	2	(4.4)	4	(2.2)
Focal Glomerulosclerosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Glycosuria	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Nephrolithiasis	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Pollakiuria	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Renal Cyst	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Renal Failure	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Renal Failure Chronic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Reproductive System And Breast Disorders	5	(11.6)	5	(11.1)	4	(8.9)	0	(0.0)	14	(7.9)
Breast Pain	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Cervical Dysplasia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dysmenorrhoea	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Erectile Dysfunction	1	(2.3)	2	(4.4)	0	(0.0)	0	(0.0)	3	(1.7)
Genital Lesion	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Menorrhagia	0	(0.0)	0	(0.0)	2	(4.4)	0	(0.0)	2	(1.1)
Pelvic Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Prostatitis	0	(0.0)	0	(0.0)	2	(4.4)	0	(0.0)	2	(1.1)

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	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Reproductive System And Breast Disorders	5	(11.6)	5	(11.1)	4	(8.9)	0	(0.0)	14	(7.9)
Testicular Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Respiratory, Thoracic And Mediastinal Disorders	11	(25.6)	7	(15.6)	9	(20.0)	6	(13.3)	33	(18.5)
Allergic Cough	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Asthma	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Cough	5	(11.6)	3	(6.7)	7	(15.6)	1	(2.2)	16	(9.0)
Dysphonia	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Dyspnoea	3	(7.0)	0	(0.0)	1	(2.2)	0	(0.0)	4	(2.2)
Increased Upper Airway Secretion	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Interstitial Lung Disease	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Lung Consolidation	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Nasal Congestion	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Paranasal Sinus Hypersecretion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Pharyngeal Erythema	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)
Pharyngolaryngeal Pain	1	(2.3)	1	(2.2)	0	(0.0)	3	(6.7)	5	(2.8)
Pleural Effusion	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Postnasal Drip	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Productive Cough	2	(4.7)	2	(4.4)	1	(2.2)	0	(0.0)	5	(2.8)
Rales	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rhinitis Allergic	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Rhinorrhoea	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Sinus Congestion	1	(2.3)	0	(0.0)	1	(2.2)	2	(4.4)	4	(2.2)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, Thoracic And Mediastinal Disorders	11	(25.6)	7	(15.6)	9	(20.0)	6	(13.3)	33	(18.5)
Sneezing	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Throat Tightness	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Skin And Subcutaneous Tissue Disorders	10	(23.3)	10	(22.2)	15	(33.3)	10	(22.2)	45	(25.3)
Acne	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Alopecia	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Blister	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Dermatitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dermatitis Allergic	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Dermatitis Contact	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Dyshidrosis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Erythema	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)
Erythema Nodosum	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hyperhidrosis	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Hypotrichosis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Lipoatrophy	1	(2.3)	1	(2.2)	0	(0.0)	1	(2.2)	3	(1.7)
Lipodystrophy Acquired	2	(4.7)	2	(4.4)	0	(0.0)	0	(0.0)	4	(2.2)
Night Sweats	0	(0.0)	1	(2.2)	1	(2.2)	3	(6.7)	5	(2.8)
Photosensitivity Reaction	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Prurigo	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pruritus	2	(4.7)	2	(4.4)	4	(8.9)	1	(2.2)	9	(5.1)
Pruritus Allergic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	10	(23.3)	10	(22.2)	15	(33.3)	10	(22.2)	45	(25.3)
Psoriasis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Rash	1	(2.3)	1	(2.2)	3	(6.7)	1	(2.2)	6	(3.4)
Rash Follicular	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Rash Generalised	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rash Macular	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Rash Maculo-Papular	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rash Papular	1	(2.3)	2	(4.4)	0	(0.0)	0	(0.0)	3	(1.7)
Rash Pruritic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Seborrhoeic Dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Skin Discolouration	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Skin Lesion	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Skin Nodule	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Skin Ulcer	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Subcutaneous Nodule	2	(4.7)	1	(2.2)	1	(2.2)	1	(2.2)	5	(2.8)
Vascular Disorders	6	(14.0)	7	(15.6)	4	(8.9)	0	(0.0)	17	(9.6)
Flushing	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Haematoma	0	(0.0)	0	(0.0)	2	(4.4)	0	(0.0)	2	(1.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular Disorders	6	(14.0)	7	(15.6)	4	(8.9)	0	(0.0)	17	(9.6)
Hyperaemia	2	(4.7)	1	(2.2)	0	(0.0)	0	(0.0)	3	(1.7)
Hypertension	2	(4.7)	6	(13.3)	1	(2.2)	0	(0.0)	9	(5.1)
Shock	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Varicose Vein	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

This table was run using a "percent incidence". This means that a row will appear on this report only if one of the columns is greater than or equal to that percentage, after rounding.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005-Define, P018-Define, P019-Define]

Appendix 2.7.4: 10

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	39	(90.7)	38	(84.4)	42	(93.3)	37	(82.2)	156	(87.6)
Patients With No Adverse Experience	4	(9.3)	7	(15.6)	3	(6.7)	8	(17.8)	22	(12.4)
Blood And Lymphatic System Disorders	3	(7.0)	4	(8.9)	7	(15.6)	4	(8.9)	18	(10.1)
Anaemia	0	(0.0)	0	(0.0)	1	(2.2)	2	(4.4)	3	(1.7)
Iron Deficiency Anaemia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Lymphadenopathy	2	(4.7)	3	(6.7)	5	(11.1)	2	(4.4)	12	(6.7)
Spleen Disorder	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Splenomegaly	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Thrombocytopenia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cardiac Disorders	0	(0.0)	2	(4.4)	4	(8.9)	4	(8.9)	10	(5.6)
Acute Myocardial Infarction	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Angina Pectoris	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Arrhythmia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Atrioventricular Block First Degree	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Bradycardia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cardio-Respiratory Arrest	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cardiovascular Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Coronary Artery Disease	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Mitral Valve Incompetence	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Palpitations	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Tachycardia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Congenital, Familial And Genetic Disorders	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Congenital, Familial And Genetic Disorders	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Porphyria	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Ear And Labyrinth Disorders	2	(4.7)	1	(2.2)	0	(0.0)	0	(0.0)	3	(1.7)
Cerumen Impaction	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Tinnitus	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vertigo	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Endocrine Disorders	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Adrenal Insufficiency	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Eye Disorders	2	(4.7)	4	(8.9)	5	(11.1)	1	(2.2)	12	(6.7)
Blindness Transient	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Cataract	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Chorioretinal Disorder	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Conjunctivitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Eye Oedema	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Ocular Icterus	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Ocular Vascular Disorder	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Papilloedema	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Photopsia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Vision Blurred	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Visual Acuity Reduced	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Visual Disturbance	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gastrointestinal Disorders	18	(41.9)	19	(42.2)	25	(55.6)	22	(48.9)	84	(47.2)
Abdominal Discomfort	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	18	(41.9)	19	(42.2)	25	(55.6)	22	(48.9)	84	(47.2)
Abdominal Distension	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Abdominal Pain	3	(7.0)	3	(6.7)	3	(6.7)	3	(6.7)	12	(6.7)
Abdominal Pain Upper	1	(2.3)	2	(4.4)	2	(4.4)	0	(0.0)	5	(2.8)
Anal Fissure	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Anogenital Dysplasia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Aphthous Stomatitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Ascites	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Cheilitis	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Constipation	3	(7.0)	1	(2.2)	1	(2.2)	1	(2.2)	6	(3.4)
Diarrhoea	10	(23.3)	4	(8.9)	5	(11.1)	8	(17.8)	27	(15.2)
Dry Mouth	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Dyspepsia	1	(2.3)	0	(0.0)	1	(2.2)	3	(6.7)	5	(2.8)
Dysphagia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Epigastric Discomfort	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Flatulence	1	(2.3)	1	(2.2)	1	(2.2)	2	(4.4)	5	(2.8)
Gastric Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Gastric Varices	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Gastritis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Gastrointestinal Disorder	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Gastrooesophageal Reflux Disease	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gingival Pain	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Glossitis	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	18	(41.9)	19	(42.2)	25	(55.6)	22	(48.9)	84	(47.2)
Glossodynia	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Haemorrhoids	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Hiatus Hernia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hypoaesthesia Oral	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Inguinal Hernia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Irritable Bowel Syndrome	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Leukoplakia Oral	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Mouth Ulceration	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Nausea	5	(11.6)	5	(11.1)	8	(17.8)	10	(22.2)	28	(15.7)
Oral Mucosal Blistering	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Oral Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Oral Soft Tissue Disorder	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pancreatitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Periodontitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Pruritus Ani	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Rectal Haemorrhage	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Stomach Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tongue Ulceration	1	(2.3)	1	(2.2)	2	(4.4)	0	(0.0)	4	(2.2)
Toothache	0	(0.0)	1	(2.2)	0	(0.0)	2	(4.4)	3	(1.7)
Vomiting	3	(7.0)	3	(6.7)	3	(6.7)	2	(4.4)	11	(6.2)
General Disorders And Administration Site Conditions	14	(32.6)	11	(24.4)	16	(35.6)	10	(22.2)	51	(28.7)
Application Site Dryness	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	14	(32.6)	11	(24.4)	16	(35.6)	10	(22.2)	51	(28.7)
Asthenia	3	(7.0)	1	(2.2)	1	(2.2)	3	(6.7)	8	(4.5)
Chest Discomfort	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)
Chest Pain	0	(0.0)	1	(2.2)	0	(0.0)	2	(4.4)	3	(1.7)
Chills	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Drug Intolerance	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Fat Tissue Increased	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Fatigue	5	(11.6)	3	(6.7)	4	(8.9)	3	(6.7)	15	(8.4)
Feeling Hot	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Infusion Site Mass	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Injection Site Bruising	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Erythema	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Injection Site Induration	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Injection Site Inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Injection Site Nodule	0	(0.0)	1	(2.2)	0	(0.0)	1	(2.2)	2	(1.1)
Injection Site Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Reaction	1	(2.3)	5	(11.1)	4	(8.9)	3	(6.7)	13	(7.3)
Irritability	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Local Swelling	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Malaise	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Nodule	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Oedema Peripheral	2	(4.7)	1	(2.2)	1	(2.2)	0	(0.0)	4	(2.2)
Pain	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	14	(32.6)	11	(24.4)	16	(35.6)	10	(22.2)	51	(28.7)
Pitting Oedema	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pyrexia	3	(7.0)	1	(2.2)	3	(6.7)	1	(2.2)	8	(4.5)
Sensation Of Pressure	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Xerosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hepatobiliary Disorders	3	(7.0)	3	(6.7)	4	(8.9)	0	(0.0)	10	(5.6)
Cholecystitis	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Hepatitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hepatomegaly	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hepatosplenomegaly	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Hyperbilirubinaemia	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Jaundice	0	(0.0)	3	(6.7)	1	(2.2)	0	(0.0)	4	(2.2)
Portal Hypertensive Gastropathy	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Immune System Disorders	2	(4.7)	0	(0.0)	1	(2.2)	2	(4.4)	5	(2.8)
Drug Hypersensitivity	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Hypersensitivity	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Jarisch-Herxheimer Reaction	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Infections And Infestations	23	(53.5)	21	(46.7)	26	(57.8)	20	(44.4)	90	(50.6)
Acarodermatitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Anogenital Warts	1	(2.3)	2	(4.4)	3	(6.7)	0	(0.0)	6	(3.4)
Bronchitis	1	(2.3)	1	(2.2)	5	(11.1)	5	(11.1)	12	(6.7)
Bronchitis Acute	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Candidiasis	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	23	(53.5)	21	(46.7)	26	(57.8)	20	(44.4)	90	(50.6)
Cellulitis	1	(2.3)	1	(2.2)	2	(4.4)	0	(0.0)	4	(2.2)
Chronic Sinusitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Dermatophytosis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Folliculitis	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Fungal Infection	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Fungal Skin Infection	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Furuncle	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Gastroenteritis	1	(2.3)	2	(4.4)	0	(0.0)	0	(0.0)	3	(1.7)
Gastroenteritis Viral	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Genital Infection Fungal	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Giardiasis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Herpes Simplex	6	(14.0)	3	(6.7)	1	(2.2)	2	(4.4)	12	(6.7)
Herpes Virus Infection	2	(4.7)	1	(2.2)	0	(0.0)	0	(0.0)	3	(1.7)
Herpes Zoster	1	(2.3)	1	(2.2)	2	(4.4)	1	(2.2)	5	(2.8)
Influenza	5	(11.6)	3	(6.7)	4	(8.9)	1	(2.2)	13	(7.3)
Injection Site Cellulitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Leishmaniasis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Lower Respiratory Tract Infection	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Nasopharyngitis	4	(9.3)	3	(6.7)	4	(8.9)	1	(2.2)	12	(6.7)
Oesophageal Candidiasis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Onychomycosis	0	(0.0)	0	(0.0)	3	(6.7)	2	(4.4)	5	(2.8)
Oral Candidiasis	2	(4.7)	1	(2.2)	2	(4.4)	0	(0.0)	5	(2.8)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	23	(53.5)	21	(46.7)	26	(57.8)	20	(44.4)	90	(50.6)
Oral Hairy Leukoplakia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Otitis Externa	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Papilloma Viral Infection	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Paronychia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pharyngitis	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)
Pneumocystis Jiroveci Pneumonia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pneumonia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pneumonia Bacterial	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pneumonia Herpes Viral	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pyoderma	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Respiratory Tract Infection	1	(2.3)	1	(2.2)	1	(2.2)	1	(2.2)	4	(2.2)
Rhinitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Secondary Syphilis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Sepsis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Sinusitis	1	(2.3)	4	(8.9)	0	(0.0)	1	(2.2)	6	(3.4)
Sinusitis Bacterial	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Skin Infection	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Staphylococcal Abscess	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Staphylococcal Infection	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)
Syphilis	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Tinea Cruris	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Tinea Pedis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Infections And Infestations	23	(53.5)	21	(46.7)	26	(57.8)	20	(44.4)	90	(50.6)
Tooth Abscess	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Tooth Infection	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Tracheitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Tracheobronchitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tuberculosis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Upper Respiratory Tract Infection	2	(4.7)	3	(6.7)	2	(4.4)	3	(6.7)	10	(5.6)
Urinary Tract Infection	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vaginal Candidiasis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vaginitis Bacterial	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Varicella	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Viral Diarrhoea	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Viral Infection	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Viral Upper Respiratory Tract Infection	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Injury, Poisoning And Procedural Complications	4	(9.3)	5	(11.1)	5	(11.1)	1	(2.2)	15	(8.4)
Arthropod Bite	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Clavicle Fracture	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Contusion	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Drug Toxicity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Excoriation	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Fibula Fracture	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hand Fracture	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Joint Injury	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Injury, Poisoning And Procedural Complications	4	(9.3)	5	(11.1)	5	(11.1)	1	(2.2)	15	(8.4)
Laceration	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Limb Injury	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Poisoning	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Post Procedural Haematoma	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Radius Fracture	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Skin Laceration	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Tibia Fracture	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Investigations	3	(7.0)	1	(2.2)	0	(0.0)	2	(4.4)	6	(3.4)
Blood Pressure Diastolic Increased	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Blood Pressure Increased	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Blood Testosterone Decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Electrocardiogram Change	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Spleen Palpable	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Weight Decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Metabolism And Nutrition Disorders	4	(9.3)	9	(20.0)	4	(8.9)	3	(6.7)	20	(11.2)
Anorexia	1	(2.3)	2	(4.4)	0	(0.0)	1	(2.2)	4	(2.2)
Central Obesity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Decreased Appetite	1	(2.3)	0	(0.0)	2	(4.4)	1	(2.2)	4	(2.2)
Diabetes Mellitus	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dyslipidaemia	2	(4.7)	2	(4.4)	1	(2.2)	0	(0.0)	5	(2.8)
Facial Wasting	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Hypercholesterolaemia	0	(0.0)	2	(4.4)	0	(0.0)	1	(2.2)	3	(1.7)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	4	(9.3)	9	(20.0)	4	(8.9)	3	(6.7)	20	(11.2)
Hyperglycaemia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Lipomatosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Metabolic Acidosis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Obesity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Musculoskeletal And Connective Tissue Disorders	11	(25.6)	8	(17.8)	6	(13.3)	7	(15.6)	32	(18.0)
Arthralgia	1	(2.3)	3	(6.7)	0	(0.0)	3	(6.7)	7	(3.9)
Arthritis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Back Pain	4	(9.3)	1	(2.2)	1	(2.2)	0	(0.0)	6	(3.4)
Bone Pain	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Bursitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Groin Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Muscle Hypertrophy	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Muscle Spasms	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Muscular Weakness	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Musculoskeletal Chest Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Musculoskeletal Pain	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Myalgia	1	(2.3)	2	(4.4)	1	(2.2)	0	(0.0)	4	(2.2)
Myositis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Neck Pain	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pain In Extremity	1	(2.3)	2	(4.4)	3	(6.7)	1	(2.2)	7	(3.9)
Plantar Fasciitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Synovial Cyst	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	11	(25.6)	8	(17.8)	6	(13.3)	7	(15.6)	32	(18.0)
Tendonitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tenosynovitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	0	(0.0)	2	(4.4)	0	(0.0)	1	(2.2)	3	(1.7)
Skin Papilloma	0	(0.0)	2	(4.4)	0	(0.0)	1	(2.2)	3	(1.7)
Nervous System Disorders	11	(25.6)	9	(20.0)	10	(22.2)	11	(24.4)	41	(23.0)
Amnesia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Aphonia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Carotid Artery Atheroma	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Disturbance In Attention	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Dizziness	1	(2.3)	3	(6.7)	1	(2.2)	0	(0.0)	5	(2.8)
Dysgeusia	2	(4.7)	1	(2.2)	1	(2.2)	1	(2.2)	5	(2.8)
Dysphasia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Facial Palsy	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Headache	5	(11.6)	4	(8.9)	5	(11.1)	5	(11.1)	19	(10.7)
Hyperreflexia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hypoaesthesia	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Hyporeflexia	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Lacunar Infarction	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Loss Of Consciousness	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Memory Impairment	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous System Disorders	11	(25.6)	9	(20.0)	10	(22.2)	11	(24.4)	41	(23.0)
Neuropathy	1	(2.3)	0	(0.0)	1	(2.2)	1	(2.2)	3	(1.7)
Neuropathy Peripheral	0	(0.0)	1	(2.2)	2	(4.4)	1	(2.2)	4	(2.2)
Paraesthesia	0	(0.0)	2	(4.4)	1	(2.2)	0	(0.0)	3	(1.7)
Radial Nerve Palsy	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Sciatica	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Sinus Headache	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Somnolence	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Syncope	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Psychiatric Disorders	9	(20.9)	5	(11.1)	5	(11.1)	5	(11.1)	24	(13.5)
Anxiety	0	(0.0)	2	(4.4)	1	(2.2)	1	(2.2)	4	(2.2)
Confusional State	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Depression	3	(7.0)	1	(2.2)	2	(4.4)	1	(2.2)	7	(3.9)
Insomnia	4	(9.3)	3	(6.7)	3	(6.7)	2	(4.4)	12	(6.7)
Mood Altered	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Sleep Disorder	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Stress	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Renal And Urinary Disorders	1	(2.3)	3	(6.7)	4	(8.9)	2	(4.4)	10	(5.6)
Bladder Spasm	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dysuria	0	(0.0)	1	(2.2)	1	(2.2)	2	(4.4)	4	(2.2)
Focal Glomerulosclerosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Glycosuria	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Nephrolithiasis	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Renal And Urinary Disorders	1	(2.3)	3	(6.7)	4	(8.9)	2	(4.4)	10	(5.6)
Pollakiuria	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Renal Cyst	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Renal Failure	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Reproductive System And Breast Disorders	5	(11.6)	3	(6.7)	4	(8.9)	0	(0.0)	12	(6.7)
Breast Pain	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Cervical Dysplasia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dysmenorrhoea	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Erectile Dysfunction	1	(2.3)	2	(4.4)	0	(0.0)	0	(0.0)	3	(1.7)
Genital Lesion	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Menorrhagia	0	(0.0)	0	(0.0)	2	(4.4)	0	(0.0)	2	(1.1)
Prostatitis	0	(0.0)	0	(0.0)	2	(4.4)	0	(0.0)	2	(1.1)
Respiratory, Thoracic And Mediastinal Disorders	10	(23.3)	7	(15.6)	7	(15.6)	6	(13.3)	30	(16.9)
Allergic Cough	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Asthma	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Cough	5	(11.6)	3	(6.7)	6	(13.3)	2	(4.4)	16	(9.0)
Dysphonia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dyspnoea	2	(4.7)	0	(0.0)	1	(2.2)	0	(0.0)	3	(1.7)
Increased Upper Airway Secretion	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Interstitial Lung Disease	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Lung Consolidation	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Nasal Congestion	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Paranasal Sinus Hypersecretion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Respiratory, Thoracic And Mediastinal Disorders	10	(23.3)	7	(15.6)	7	(15.6)	6	(13.3)	30	(16.9)
Pharyngeal Erythema	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)
Pharyngolaryngeal Pain	1	(2.3)	1	(2.2)	0	(0.0)	3	(6.7)	5	(2.8)
Postnasal Drip	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Productive Cough	2	(4.7)	2	(4.4)	1	(2.2)	0	(0.0)	5	(2.8)
Rales	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rhinitis Allergic	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Rhinorrhoea	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Sinus Congestion	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
Sneezing	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Throat Tightness	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Skin And Subcutaneous Tissue Disorders	10	(23.3)	9	(20.0)	13	(28.9)	10	(22.2)	42	(23.6)
Acne	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Alopecia	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Blister	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Dermatitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dermatitis Allergic	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Dermatitis Contact	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Erythema	1	(2.3)	1	(2.2)	2	(4.4)	0	(0.0)	4	(2.2)
Erythema Nodosum	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hyperhidrosis	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Hypotrichosis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Lipoatrophy	0	(0.0)	1	(2.2)	0	(0.0)	1	(2.2)	2	(1.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	10	(23.3)	9	(20.0)	13	(28.9)	10	(22.2)	42	(23.6)
Lipodystrophy Acquired	2	(4.7)	2	(4.4)	0	(0.0)	0	(0.0)	4	(2.2)
Night Sweats	0	(0.0)	1	(2.2)	1	(2.2)	3	(6.7)	5	(2.8)
Photosensitivity Reaction	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Prurigo	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pruritus	2	(4.7)	2	(4.4)	4	(8.9)	1	(2.2)	9	(5.1)
Psoriasis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Rash	1	(2.3)	0	(0.0)	3	(6.7)	1	(2.2)	5	(2.8)
Rash Follicular	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Rash Generalised	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rash Macular	1	(2.3)	0	(0.0)	1	(2.2)	1	(2.2)	3	(1.7)
Rash Maculo-Papular	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rash Papular	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Rash Pruritic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Seborrhoeic Dermatitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Skin Discolouration	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Skin Lesion	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Skin Nodule	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Skin Ulcer	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Subcutaneous Nodule	2	(4.7)	1	(2.2)	1	(2.2)	1	(2.2)	5	(2.8)
Vascular Disorders	5	(11.6)	7	(15.6)	4	(8.9)	0	(0.0)	16	(9.0)
Flushing	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Haematoma	0	(0.0)	0	(0.0)	2	(4.4)	0	(0.0)	2	(1.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular Disorders	5	(11.6)	7	(15.6)	4	(8.9)	0	(0.0)	16	(9.0)
Hyperaemia	2	(4.7)	1	(2.2)	0	(0.0)	0	(0.0)	3	(1.7)
Hypertension	1	(2.3)	6	(13.3)	1	(2.2)	0	(0.0)	8	(4.5)
Shock	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Varicose Vein	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.
This table was run using a "percent incidence". This means that a row will appear on this report only if one of the columns is greater than or equal to that percentage, after rounding.
Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).
Adverse experience terms are from MedDRA Version 9.0.

[Ref. 5.3.5.1: P005]

Appendix 2.7.4: 11

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	13	(30.2)	11	(24.4)	18	(40.0)	16	(35.6)	58	(32.6)
Patients With No Adverse Experience	30	(69.8)	34	(75.6)	27	(60.0)	29	(64.4)	120	(67.4)
Blood And Lymphatic System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Cardiac Disorders	0	(0.0)	1	(2.2)	0	(0.0)	2	(4.4)	3	(1.7)
Arrhythmia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Cardiovascular Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Palpitations	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Eye Disorders	1	(2.3)	0	(0.0)	2	(4.4)	0	(0.0)	3	(1.7)
Ocular Icterus	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Vision Blurred	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gastrointestinal Disorders	5	(11.6)	3	(6.7)	2	(4.4)	6	(13.3)	16	(9.0)
Abdominal Pain	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Cheilitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Diarrhoea	2	(4.7)	1	(2.2)	0	(0.0)	3	(6.7)	6	(3.4)
Dry Mouth	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Dyspepsia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Flatulence	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Gastrooesophageal Reflux Disease	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Glossitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Nausea	2	(4.7)	0	(0.0)	0	(0.0)	2	(4.4)	4	(2.2)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	5	(11.6)	3	(6.7)	2	(4.4)	6	(13.3)	16	(9.0)
Pancreatitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Stomach Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Vomiting	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
General Disorders And Administration Site Conditions	3	(7.0)	2	(4.4)	6	(13.3)	3	(6.7)	14	(7.9)
Drug Intolerance	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Fat Tissue Increased	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Fatigue	2	(4.7)	0	(0.0)	3	(6.7)	0	(0.0)	5	(2.8)
Feeling Hot	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Erythema	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Injection Site Nodule	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Reaction	1	(2.3)	0	(0.0)	2	(4.4)	1	(2.2)	4	(2.2)
Immune System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Drug Hypersensitivity	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Hypersensitivity	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Infections And Infestations	0	(0.0)	0	(0.0)	2	(4.4)	0	(0.0)	2	(1.1)
Cellulitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Injection Site Cellulitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Weight Decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	2	(4.7)	3	(6.7)	2	(4.4)	1	(2.2)	8	(4.5)
Central Obesity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dyslipidaemia	2	(4.7)	1	(2.2)	1	(2.2)	0	(0.0)	4	(2.2)
Facial Wasting	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hypercholesterolaemia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Metabolic Acidosis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Musculoskeletal And Connective Tissue Disorders	0	(0.0)	4	(8.9)	0	(0.0)	0	(0.0)	4	(2.2)
Arthralgia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Muscle Atrophy	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Muscle Spasms	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Myalgia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Nervous System Disorders	4	(9.3)	2	(4.4)	4	(8.9)	3	(6.7)	13	(7.3)
Amnesia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Disturbance In Attention	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Dizziness	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Dysgeusia	2	(4.7)	0	(0.0)	0	(0.0)	1	(2.2)	3	(1.7)
Headache	3	(7.0)	0	(0.0)	3	(6.7)	1	(2.2)	7	(3.9)
Memory Impairment	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Neuropathy	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Paraesthesia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Somnolence	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous System Disorders	4	(9.3)	2	(4.4)	4	(8.9)	3	(6.7)	13	(7.3)
Syncope	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Psychiatric Disorders	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Depression	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Insomnia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Nervousness	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Renal And Urinary Disorders	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)
Nephrolithiasis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pollakiuria	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Renal Failure	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Reproductive System And Breast Disorders	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Erectile Dysfunction	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Skin And Subcutaneous Tissue Disorders	2	(4.7)	2	(4.4)	4	(8.9)	4	(8.9)	12	(6.7)
Erythema	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hyperhidrosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Lipoatrophy	1	(2.3)	1	(2.2)	0	(0.0)	1	(2.2)	3	(1.7)
Lipodystrophy Acquired	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Pruritus	0	(0.0)	0	(0.0)	3	(6.7)	0	(0.0)	3	(1.7)
Rash Generalised	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rash Macular	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Rash Pruritic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Skin Nodule	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	2	(4.7)	2	(4.4)	4	(8.9)	4	(8.9)	12	(6.7)
Subcutaneous Nodule	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005-Define]

Appendix 2.7.4: 12

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Double-Blind Phase) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	11	(25.6)	9	(20.0)	15	(33.3)	15	(33.3)	50	(28.1)
Patients With No Adverse Experience	32	(74.4)	36	(80.0)	30	(66.7)	30	(66.7)	128	(71.9)
Blood And Lymphatic System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Cardiac Disorders	0	(0.0)	1	(2.2)	0	(0.0)	2	(4.4)	3	(1.7)
Arrhythmia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Cardiovascular Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Palpitations	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Eye Disorders	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Ocular Icterus	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vision Blurred	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gastrointestinal Disorders	5	(11.6)	3	(6.7)	2	(4.4)	6	(13.3)	16	(9.0)
Abdominal Pain	0	(0.0)	1	(2.2)	1	(2.2)	1	(2.2)	3	(1.7)
Cheilitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Diarrhoea	2	(4.7)	1	(2.2)	0	(0.0)	3	(6.7)	6	(3.4)
Dry Mouth	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Dyspepsia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Flatulence	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Gastrooesophageal Reflux Disease	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Glossitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Nausea	2	(4.7)	0	(0.0)	0	(0.0)	2	(4.4)	4	(2.2)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Double-Blind Phase) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	5	(11.6)	3	(6.7)	2	(4.4)	6	(13.3)	16	(9.0)
Pancreatitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Stomach Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Vomiting	1	(2.3)	0	(0.0)	0	(0.0)	1	(2.2)	2	(1.1)
General Disorders And Administration Site Conditions	2	(4.7)	2	(4.4)	4	(8.9)	3	(6.7)	11	(6.2)
Drug Intolerance	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Fatigue	2	(4.7)	0	(0.0)	2	(4.4)	0	(0.0)	4	(2.2)
Feeling Hot	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Erythema	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Injection Site Reaction	0	(0.0)	0	(0.0)	2	(4.4)	1	(2.2)	3	(1.7)
Hepatobiliary Disorders	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Jaundice	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Immune System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Hypersensitivity	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Infections And Infestations	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cellulitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Weight Decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Metabolism And Nutrition Disorders	2	(4.7)	3	(6.7)	2	(4.4)	1	(2.2)	8	(4.5)
Central Obesity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Dyslipidaemia	2	(4.7)	1	(2.2)	1	(2.2)	0	(0.0)	4	(2.2)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Double-Blind Phase) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	2	(4.7)	3	(6.7)	2	(4.4)	1	(2.2)	8	(4.5)
Facial Wasting	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hypercholesterolaemia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Metabolic Acidosis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Musculoskeletal And Connective Tissue Disorders	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)
Arthralgia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Myalgia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Nervous System Disorders	4	(9.3)	2	(4.4)	3	(6.7)	3	(6.7)	12	(6.7)
Amnesia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Disturbance In Attention	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Dizziness	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Dysgeusia	2	(4.7)	0	(0.0)	0	(0.0)	1	(2.2)	3	(1.7)
Headache	3	(7.0)	0	(0.0)	2	(4.4)	1	(2.2)	6	(3.4)
Memory Impairment	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Neuropathy	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Paraesthesia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Somnolence	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Syncope	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Psychiatric Disorders	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Depression	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Renal And Urinary Disorders	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Protocol 005: Substudies A and B Combined; Double-Blind Phase) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Renal And Urinary Disorders	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)
Nephrolithiasis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pollakiuria	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Renal Failure	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Reproductive System And Breast Disorders	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Erectile Dysfunction	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Skin And Subcutaneous Tissue Disorders	0	(0.0)	2	(4.4)	4	(8.9)	4	(8.9)	10	(5.6)
Hyperhidrosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Lipoatrophy	0	(0.0)	1	(2.2)	0	(0.0)	1	(2.2)	2	(1.1)
Lipodystrophy Acquired	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)
Pruritus	0	(0.0)	0	(0.0)	3	(6.7)	0	(0.0)	3	(1.7)
Rash Generalised	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rash Macular	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Rash Pruritic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Skin Nodule	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Subcutaneous Nodule	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)

Although a patient may have had two or more drug-related clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.0.

[Ref. 5.3.5.1: P005]

Appendix 2.7.4: 13
Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	21	(48.8)	21	(46.7)	27	(60.0)	25	(55.6)	94	(52.8)
Patients With No Adverse Experience	22	(51.2)	24	(53.3)	18	(40.0)	20	(44.4)	84	(47.2)
Blood And Lymphatic System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Cardiac Disorders	0	(0.0)	1	(2.2)	1	(2.2)	2	(4.4)	4	(2.2)
Arrhythmia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Cardiovascular Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Palpitations	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Tachycardia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Ear And Labyrinth Disorders	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vertigo	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Eye Disorders	1	(2.3)	0	(0.0)	2	(4.4)	0	(0.0)	3	(1.7)
Ocular Icterus	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Vision Blurred	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gastrointestinal Disorders	9	(20.9)	5	(11.1)	11	(24.4)	14	(31.1)	39	(21.9)
Abdominal Discomfort	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Abdominal Distension	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Abdominal Pain	0	(0.0)	1	(2.2)	2	(4.4)	2	(4.4)	5	(2.8)
Abdominal Pain Upper	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Aphthous Stomatitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cheilitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	9	(20.9)	5	(11.1)	11	(24.4)	14	(31.1)	39	(21.9)
Constipation	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Diarrhoea	7	(16.3)	1	(2.2)	0	(0.0)	7	(15.6)	15	(8.4)
Dry Mouth	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Dyspepsia	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Epigastric Discomfort	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Flatulence	1	(2.3)	0	(0.0)	1	(2.2)	1	(2.2)	3	(1.7)
Gastric Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Gastrooesophageal Reflux Disease	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gingival Pain	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Glossitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hypoaesthesia Oral	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Nausea	4	(9.3)	2	(4.4)	5	(11.1)	5	(11.1)	16	(9.0)
Oral Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pancreatitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Stomach Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tongue Ulceration	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Vomiting	3	(7.0)	2	(4.4)	1	(2.2)	1	(2.2)	7	(3.9)
General Disorders And Administration Site Conditions	8	(18.6)	7	(15.6)	12	(26.7)	7	(15.6)	34	(19.1)
Application Site Dryness	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Drug Intolerance	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Fat Tissue Increased	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	8	(18.6)	7	(15.6)	12	(26.7)	7	(15.6)	34	(19.1)
Fatigue	4	(9.3)	0	(0.0)	3	(6.7)	1	(2.2)	8	(4.5)
Feeling Hot	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Injection Site Bruising	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Erythema	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Injection Site Induration	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Injection Site Inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Injection Site Nodule	1	(2.3)	1	(2.2)	0	(0.0)	1	(2.2)	3	(1.7)
Injection Site Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Injection Site Reaction	2	(4.7)	4	(8.9)	4	(8.9)	3	(6.7)	13	(7.3)
Nodule	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pyrexia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Xerosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hepatobiliary Disorders	0	(0.0)	3	(6.7)	1	(2.2)	0	(0.0)	4	(2.2)
Hyperbilirubinaemia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Jaundice	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)
Immune System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Drug Hypersensitivity	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Hypersensitivity	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Infections And Infestations	0	(0.0)	1	(2.2)	2	(4.4)	0	(0.0)	3	(1.7)
Cellulitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Injection Site Cellulitis	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Weight Decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Metabolism And Nutrition Disorders	2	(4.7)	4	(8.9)	4	(8.9)	2	(4.4)	12	(6.7)
Central Obesity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Decreased Appetite	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Dyslipidaemia	2	(4.7)	1	(2.2)	1	(2.2)	0	(0.0)	4	(2.2)
Facial Wasting	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Hypercholesterolaemia	0	(0.0)	2	(4.4)	0	(0.0)	1	(2.2)	3	(1.7)
Hypophosphataemia	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Metabolic Acidosis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Musculoskeletal And Connective Tissue Disorders	1	(2.3)	4	(8.9)	1	(2.2)	1	(2.2)	7	(3.9)
Arthralgia	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Muscle Atrophy	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Muscle Hypertrophy	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Muscle Spasms	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Myalgia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Pain In Extremity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Nervous System Disorders	5	(11.6)	3	(6.7)	7	(15.6)	6	(13.3)	21	(11.8)
Amnesia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Disturbance In Attention	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Dizziness	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Dysgeusia	2	(4.7)	1	(2.2)	1	(2.2)	1	(2.2)	5	(2.8)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Nervous System Disorders	5	(11.6)	3	(6.7)	7	(15.6)	6	(13.3)	21	(11.8)
Headache	4	(9.3)	0	(0.0)	3	(6.7)	3	(6.7)	10	(5.6)
Hypoaesthesia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Lacunar Infarction	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Memory Impairment	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Neuropathy	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Neuropathy Peripheral	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Paraesthesia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Somnolence	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Syncope	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Psychiatric Disorders	3	(7.0)	1	(2.2)	1	(2.2)	0	(0.0)	5	(2.8)
Depression	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Insomnia	1	(2.3)	1	(2.2)	1	(2.2)	0	(0.0)	3	(1.7)
Nervousness	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Sleep Disorder	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Renal And Urinary Disorders	1	(2.3)	1	(2.2)	3	(6.7)	1	(2.2)	6	(3.4)
Dysuria	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Nephrolithiasis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pollakiuria	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Renal Failure	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Renal Failure Chronic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Reproductive System And Breast Disorders	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Erectile Dysfunction	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Respiratory, Thoracic And Mediastinal Disorders	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pharyngeal Erythema	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Skin And Subcutaneous Tissue Disorders	5	(11.6)	5	(11.1)	5	(11.1)	4	(8.9)	19	(10.7)
Alopecia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Erythema	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hyperhidrosis	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Lipoatrophy	1	(2.3)	1	(2.2)	0	(0.0)	1	(2.2)	3	(1.7)
Lipodystrophy Acquired	1	(2.3)	2	(4.4)	0	(0.0)	0	(0.0)	3	(1.7)
Photosensitivity Reaction	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pruritus	1	(2.3)	2	(4.4)	3	(6.7)	0	(0.0)	6	(3.4)
Rash Generalised	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rash Macular	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Rash Papular	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Rash Pruritic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Skin Lesion	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Skin Nodule	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Subcutaneous Nodule	1	(2.3)	1	(2.2)	1	(2.2)	1	(2.2)	4	(2.2)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Vascular Disorders	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Flushing	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)

Although a patient may have had two or more drug-related clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005-Define]

Appendix 2.7.4: 14
Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Patients With One Or More Drug-Related Adverse Experiences	18	(41.9)	19	(42.2)	24	(53.3)	24	(53.3)	85	(47.8)
Patients With No Drug-Related Adverse Experience	25	(58.1)	26	(57.8)	21	(46.7)	21	(46.7)	93	(52.2)
Blood And Lymphatic System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Anaemia	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Cardiac Disorders	0	(0.0)	1	(2.2)	1	(2.2)	2	(4.4)	4	(2.2)
Arrhythmia	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Cardiovascular Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Palpitations	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Tachycardia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Ear And Labyrinth Disorders	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vertigo	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Eye Disorders	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Ocular Icterus	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Vision Blurred	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gastrointestinal Disorders	7	(16.3)	5	(11.1)	11	(24.4)	14	(31.1)	37	(20.8)
Abdominal Discomfort	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Abdominal Distension	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Abdominal Pain	0	(0.0)	1	(2.2)	2	(4.4)	2	(4.4)	5	(2.8)
Abdominal Pain Upper	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Aphthous Stomatitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cheilitis	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Constipation	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	7	(16.3)	5	(11.1)	11	(24.4)	14	(31.1)	37	(20.8)
Diarrhoea	5	(11.6)	1	(2.2)	0	(0.0)	7	(15.6)	13	(7.3)
Dry Mouth	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Dyspepsia	0	(0.0)	0	(0.0)	0	(0.0)	2	(4.4)	2	(1.1)
Epigastric Discomfort	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Flatulence	1	(2.3)	0	(0.0)	1	(2.2)	1	(2.2)	3	(1.7)
Gastric Disorder	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Gastrooesophageal Reflux Disease	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Gingival Pain	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Glossitis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hypoaesthesia Oral	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Nausea	4	(9.3)	2	(4.4)	5	(11.1)	5	(11.1)	16	(9.0)
Oral Pain	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pancreatitis Acute	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Stomach Discomfort	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Tongue Ulceration	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Vomiting	3	(7.0)	2	(4.4)	1	(2.2)	1	(2.2)	7	(3.9)
General Disorders And Administration Site Conditions	7	(16.3)	6	(13.3)	10	(22.2)	7	(15.6)	30	(16.9)
Application Site Dryness	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Drug Intolerance	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Fatigue	4	(9.3)	0	(0.0)	2	(4.4)	1	(2.2)	7	(3.9)
Feeling Hot	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Injection Site Erythema	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)

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(Protocol 005: Substudies A and B Combined Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	7	(16.3)	6	(13.3)	10	(22.2)	7	(15.6)	30	(16.9)
Injection Site Induration	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Injection Site Inflammation	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Injection Site Nodule	0	(0.0)	1	(2.2)	0	(0.0)	1	(2.2)	2	(1.1)
Injection Site Reaction	1	(2.3)	3	(6.7)	4	(8.9)	3	(6.7)	11	(6.2)
Nodule	1	(2.3)	0	(0.0)	1	(2.2)	0	(0.0)	2	(1.1)
Pyrexia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Xerosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Hepatobiliary Disorders	0	(0.0)	2	(4.4)	2	(4.4)	0	(0.0)	4	(2.2)
Hyperbilirubinaemia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Jaundice	0	(0.0)	2	(4.4)	1	(2.2)	0	(0.0)	3	(1.7)
Immune System Disorders	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Hypersensitivity	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Infections And Infestations	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Cellulitis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Investigations	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Weight Decreased	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Metabolism And Nutrition Disorders	2	(4.7)	5	(11.1)	4	(8.9)	2	(4.4)	13	(7.3)
Central Obesity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Decreased Appetite	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)
Dyslipidaemia	2	(4.7)	1	(2.2)	1	(2.2)	0	(0.0)	4	(2.2)
Facial Wasting	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Hypercholesterolaemia	0	(0.0)	1	(2.2)	0	(0.0)	1	(2.2)	2	(1.1)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	2	(4.7)	5	(11.1)	4	(8.9)	2	(4.4)	13	(7.3)
Lipomatosis	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Metabolic Acidosis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Musculoskeletal And Connective Tissue Disorders	1	(2.3)	2	(4.4)	1	(2.2)	1	(2.2)	5	(2.8)
Arthralgia	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Muscle Hypertrophy	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Myalgia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Pain In Extremity	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Nervous System Disorders	5	(11.6)	3	(6.7)	5	(11.1)	6	(13.3)	19	(10.7)
Amnesia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Disturbance In Attention	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Dizziness	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Dysgeusia	2	(4.7)	1	(2.2)	1	(2.2)	1	(2.2)	5	(2.8)
Headache	4	(9.3)	0	(0.0)	2	(4.4)	3	(6.7)	9	(5.1)
Lacunar Infarction	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Memory Impairment	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Migraine	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Neuropathy	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Neuropathy Peripheral	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Paraesthesia	0	(0.0)	1	(2.2)	1	(2.2)	0	(0.0)	2	(1.1)
Radial Nerve Palsy	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Somnolence	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Syncope	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Psychiatric Disorders	3	(7.0)	1	(2.2)	0	(0.0)	0	(0.0)	4	(2.2)
Depression	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Insomnia	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Sleep Disorder	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Renal And Urinary Disorders	1	(2.3)	1	(2.2)	2	(4.4)	1	(2.2)	5	(2.8)
Dysuria	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Nephrolithiasis	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Pollakiuria	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Renal Failure	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Reproductive System And Breast Disorders	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Erectile Dysfunction	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Respiratory, Thoracic And Mediastinal Disorders	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Pharyngeal Erythema	0	(0.0)	1	(2.2)	0	(0.0)	0	(0.0)	1	(0.6)
Skin And Subcutaneous Tissue Disorders	3	(7.0)	5	(11.1)	5	(11.1)	4	(8.9)	17	(9.6)
Alopecia	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Erythema	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Hyperhidrosis	1	(2.3)	1	(2.2)	0	(0.0)	0	(0.0)	2	(1.1)
Lipoatrophy	0	(0.0)	1	(2.2)	0	(0.0)	1	(2.2)	2	(1.1)
Lipodystrophy Acquired	0	(0.0)	2	(4.4)	0	(0.0)	0	(0.0)	2	(1.1)
Photosensitivity Reaction	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Pruritus	1	(2.3)	2	(4.4)	3	(6.7)	0	(0.0)	6	(3.4)
Rash Generalised	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Rash Macular	0	(0.0)	0	(0.0)	1	(2.2)	1	(2.2)	2	(1.1)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class
(Protocol 005: Substudies A and B Combined Entire Study Period) - *Original Application*

	MK-0518 200 mg b.i.d. (N = 43)		MK-0518 400 mg b.i.d. (N = 45)		MK-0518 600 mg b.i.d. (N = 45)		Placebo (N = 45)		Total (N = 178)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	3	(7.0)	5	(11.1)	5	(11.1)	4	(8.9)	17	(9.6)
Rash Papular	1	(2.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(0.6)
Rash Pruritic	0	(0.0)	0	(0.0)	1	(2.2)	0	(0.0)	1	(0.6)
Skin Nodule	0	(0.0)	0	(0.0)	0	(0.0)	1	(2.2)	1	(0.6)
Subcutaneous Nodule	1	(2.3)	1	(2.2)	1	(2.2)	1	(2.2)	4	(2.2)
Vascular Disorders	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)
Flushing	2	(4.7)	0	(0.0)	0	(0.0)	0	(0.0)	2	(1.1)

Although a patient may have had two or more drug-related clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005]

Appendix 2.7.4: 15
Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N=43)		MK-0518 400 mg b.i.d. (N=45)		MK-0518 600 mg b.i.d. (N=45)		Placebo (N=45)		Total (N=178)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Patients with one or more adverse experiences	11/43	(25.6)	13/45	(28.9)	16/45	(35.6)	11/45	(24.4)	51/178	(28.7)
Patients with no adverse experiences	32/43	(74.4)	32/45	(71.1)	29/45	(64.4)	34/45	(75.6)	127/178	(71.3)
Blood Chemistry Test	**10/43**	**(23.3)**	**11/45**	**(24.4)**	**15/45**	**(33.3)**	**8/45**	**(17.8)**	**44/178**	(24.7)
Alanine aminotransferase increased	3/43	(7.0)	2/45	(4.4)	0/45	(0.0)	0/45	(0.0)	5/178	(2.8)
Alkaline phosphatase increased	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Aspartate aminotransferase increased	3/43	(7.0)	3/45	(6.7)	0/45	(0.0)	0/45	(0.0)	6/178	(3.4)
Blood amylase increased	1/43	(2.3)	1/45	(2.2)	2/45	(4.4)	0/45	(0.0)	4/178	(2.2)
Blood bilirubin increased	4/43	(9.3)	4/45	(8.9)	4/45	(8.9)	2/45	(4.4)	14/178	(7.9)
Blood bilirubin indirect increased	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Blood cholesterol increased	1/42	(2.4)	1/45	(2.2)	1/45	(2.2)	3/45	(6.7)	6/177	(3.4)
Blood creatinine increased	1/43	(2.3)	3/45	(6.7)	0/45	(0.0)	1/45	(2.2)	5/178	(2.8)
Blood glucose increased	3/43	(7.0)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	3/178	(1.7)
Blood lactic acid increased	0/1	(0.0)	1/1	(100.0)	1/1	(100.0)	0/1	(0.0)	2/4	(50.0)
Blood pancreatic amylase increased	0/2	(0.0)	1/3	(33.3)	2/4	(50.0)	0/1	(0.0)	3/10	(30.0)
Blood phosphorus decreased	0/43	(0.0)	1/45	(2.2)	1/45	(2.2)	2/45	(4.4)	4/178	(2.2)
Blood potassium decreased	0/43	(0.0)	1/45	(2.2)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Blood triglycerides increased	2/42	(4.8)	1/45	(2.2)	2/45	(4.4)	2/45	(4.4)	7/177	(4.0)
Blood urea nitrogen increased	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Creatine phosphokinase increased	0/43	(0.0)	5/45	(11.1)	5/45	(11.1)	0/45	(0.0)	10/178	(5.6)
Fasting blood glucose increased	0/42	(0.0)	0/45	(0.0)	2/45	(4.4)	0/45	(0.0)	2/177	(1.1)
Lipase increased	2/43	(4.7)	2/45	(4.4)	2/45	(4.4)	0/45	(0.0)	6/178	(3.4)

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N=43)		MK-0518 400 mg b.i.d. (N=45)		MK-0518 600 mg b.i.d. (N=45)		Placebo (N=45)		Total (N=178)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Blood Chemistry Test	**10/43**	**(23.3)**	**11/45**	**(24.4)**	**15/45**	**(33.3)**	**8/45**	**(17.8)**	**44/178**	(24.7)
Low density lipoprotein increased	1/40	(2.5)	1/43	(2.3)	1/45	(2.2)	1/44	(2.3)	4/172	(2.3)
Protein total increased	0/43	(0.0)	0/45	(0.0)	1/45	(2.2)	0/45	(0.0)	1/178	(0.6)
Clinical Serology Test	**0/11**	**(0.0)**	**1/5**	**(20.0)**	**0/6**	**(0.0)**	**0/10**	**(0.0)**	**1/32**	(3.1)
Human papilloma virus antibody positive	0/†		1/1	(100.0)	0/†		0/†		1/1	(100.0)
Endocrine Test	**1/9**	**(11.1)**	**0/7**	**(0.0)**	**0/6**	**(0.0)**	**0/5**	**(0.0)**	**1/27**	(3.7)
Blood testosterone decreased	1/1	(100.0)	0/†		0/†		0/†		1/1	(100.0)
Hematology Laboratory Test	**2/43**	**(4.7)**	**1/45**	**(2.2)**	**5/45**	**(11.1)**	**3/45**	**(6.7)**	**11/178**	(6.2)
Absolute lymphocyte count decreased	0/43	(0.0)	0/45	(0.0)	0/45	(0.0)	1/45	(2.2)	1/178	(0.6)
Absolute neutrophil count decreased	1/43	(2.3)	0/45	(0.0)	2/45	(4.4)	2/45	(4.4)	5/178	(2.8)
Blood iron decreased	0/†		0/†		1/1	(100.0)	0/†		1/1	(100.0)
Ferritin decreased	0/†		0/†		1/1	(100.0)	0/†		1/1	(100.0)
Platelet count decreased	2/43	(4.7)	0/45	(0.0)	1/45	(2.2)	0/45	(0.0)	3/178	(1.7)
Red blood cell count decreased	0/43	(0.0)	1/45	(2.2)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
White blood cell count decreased	0/43	(0.0)	0/45	(0.0)	0/45	(0.0)	1/45	(2.2)	1/178	(0.6)
White blood cell count increased	0/43	(0.0)	0/45	(0.0)	1/45	(2.2)	0/45	(0.0)	1/178	(0.6)
Urinalysis Test	**1/43**	**(2.3)**	**2/45**	**(4.4)**	**2/45**	**(4.4)**	**2/45**	**(4.4)**	**7/178**	(3.9)
Blood urine present	0/43	(0.0)	0/45	(0.0)	2/45	(4.4)	1/45	(2.2)	3/178	(1.7)

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N=43)		MK-0518 400 mg b.i.d. (N=45)		MK-0518 600 mg b.i.d. (N=45)		Placebo (N=45)		Total (N=178)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Urinalysis Test	**1/43**	**(2.3)**	**2/45**	**(4.4)**	**2/45**	**(4.4)**	**2/45**	**(4.4)**	**7/178**	(3.9)
Glucose urine present	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Protein urine present	1/43	(2.3)	1/45	(2.2)	0/45	(0.0)	1/45	(2.2)	3/178	(1.7)
Red blood cells urine positive	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Urine drug screen positive	0/†		1/1	(100.0)	0/†		0/†		1/1	(100.0)

† indicates there was no associated laboratory test or there were no patients for whom the laboratory test was recorded postbaseline.

n/m = number of patients with laboratory adverse experiences / number of patients for whom the laboratory test was recorded postbaseline.

Although a patient may have had two or more laboratory adverse experiences, the patient is counted only once in a category. The same patient may appear in different categories.

This table was run using a "percent incidence". This means that a row will appear on this report only if one of the columns is greater than or equal to that percentage, after rounding.
Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005-Define]

Appendix 2.7.4: 16
Number (%) of Patients With Specific Drug-Related Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N=43)		MK-0518 400 mg b.i.d. (N=45)		MK-0518 600 mg b.i.d. (N=45)		Placebo (N=45)		Total (N=178)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Patients with one or more adverse experiences	8/43	(18.6)	9/45	(20.0)	9/45	(20.0)	8/45	(17.8)	34/178	(19.1)
Patients with no adverse experiences	35/43	(81.4)	36/45	(80.0)	36/45	(80.0)	37/45	(82.2)	144/178	(80.9)
Blood Chemistry Test	**8/43**	**(18.6)**	**9/45**	**(20.0)**	**8/45**	**(17.8)**	**7/45**	**(15.6)**	**32/178**	(18.0)
Alanine aminotransferase increased	2/43	(4.7)	1/45	(2.2)	0/45	(0.0)	0/45	(0.0)	3/178	(1.7)
Aspartate aminotransferase increased	2/43	(4.7)	2/45	(4.4)	0/45	(0.0)	0/45	(0.0)	4/178	(2.2)
Blood amylase increased	0/43	(0.0)	1/45	(2.2)	1/45	(2.2)	0/45	(0.0)	2/178	(1.1)
Blood bilirubin increased	4/43	(9.3)	4/45	(8.9)	4/45	(8.9)	2/45	(4.4)	14/178	(7.9)
Blood bilirubin indirect increased	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Blood cholesterol increased	0/42	(0.0)	1/45	(2.2)	0/45	(0.0)	3/45	(6.7)	4/177	(2.3)
Blood creatinine increased	1/43	(2.3)	2/45	(4.4)	0/45	(0.0)	1/45	(2.2)	4/178	(2.2)
Blood glucose increased	2/43	(4.7)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	2/178	(1.1)
Blood lactic acid increased	0/1	(0.0)	1/1	(100.0)	1/1	(100.0)	0/1	(0.0)	2/4	(50.0)
Blood pancreatic amylase increased	0/2	(0.0)	1/3	(33.3)	1/4	(25.0)	0/1	(0.0)	2/10	(20.0)
Blood phosphorus decreased	0/43	(0.0)	0/45	(0.0)	0/45	(0.0)	2/45	(4.4)	2/178	(1.1)
Blood triglycerides increased	0/42	(0.0)	0/45	(0.0)	0/45	(0.0)	1/45	(2.2)	1/177	(0.6)
Creatine phosphokinase increased	0/43	(0.0)	2/45	(4.4)	1/45	(2.2)	0/45	(0.0)	3/178	(1.7)
Fasting blood glucose increased	0/42	(0.0)	0/45	(0.0)	1/45	(2.2)	0/45	(0.0)	1/177	(0.6)
Lipase increased	2/43	(4.7)	2/45	(4.4)	1/45	(2.2)	0/45	(0.0)	5/178	(2.8)
Low density lipoprotein increased	0/40	(0.0)	1/43	(2.3)	0/45	(0.0)	1/44	(2.3)	2/172	(1.2)
Hematology Laboratory Test	**1/43**	**(2.3)**	**0/45**	**(0.0)**	**3/45**	**(6.7)**	**1/45**	**(2.2)**	**5/178**	(2.8)

Number (%) of Patients With Specific Drug-Related Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category (Protocol 005: Substudies A and B Combined Entire Study Period) - *Cumulative Data*

	MK-0518 200 mg b.i.d. (N=43)		MK-0518 400 mg b.i.d. (N=45)		MK-0518 600 mg b.i.d. (N=45)		Placebo (N=45)		Total (N=178)	
	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)	n/m	(%)
Hematology Laboratory Test	**1/43**	**(2.3)**	**0/45**	**(0.0)**	**3/45**	**(6.7)**	**1/45**	**(2.2)**	**5/178**	(2.8)
Absolute lymphocyte count decreased	0/43	(0.0)	0/45	(0.0)	0/45	(0.0)	1/45	(2.2)	1/178	(0.6)
Absolute neutrophil count decreased	0/43	(0.0)	0/45	(0.0)	2/45	(4.4)	0/45	(0.0)	2/178	(1.1)
Platelet count decreased	1/43	(2.3)	0/45	(0.0)	1/45	(2.2)	0/45	(0.0)	2/178	(1.1)
Urinalysis Test	**1/43**	**(2.3)**	**0/45**	**(0.0)**	**1/45**	**(2.2)**	**0/45**	**(0.0)**	**2/178**	(1.1)
Blood urine present	0/43	(0.0)	0/45	(0.0)	1/45	(2.2)	0/45	(0.0)	1/178	(0.6)
Glucose urine present	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Protein urine present	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)
Red blood cells urine positive	1/43	(2.3)	0/45	(0.0)	0/45	(0.0)	0/45	(0.0)	1/178	(0.6)

† indicates there was no associated laboratory test or there were no patients for whom the laboratory test was recorded postbaseline.

n/m = number of patients with laboratory adverse experiences / number of patients for whom the laboratory test was recorded postbaseline.

Although a patient may have had two or more laboratory adverse experiences, the patient is counted only once in a category. The same patient may appear in different categories.

This table was run using a "percent incidence". This means that a row will appear on this report only if one of the columns is greater than or equal to that percentage, after rounding.
Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005-Define]

Appendix 2.7.4: 17

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	426	(84.0)	243	(86.2)	669	(84.8)
Patients With No Adverse Experience	81	(16.0)	39	(13.8)	120	(15.2)
Blood And Lymphatic System Disorders	35	(6.9)	20	(7.1)	55	(7.0)
Anaemia	11	(2.2)	8	(2.8)	19	(2.4)
Anaemia Macrocytic	1	(0.2)	0	(0.0)	1	(0.1)
Haemolytic Anaemia	1	(0.2)	0	(0.0)	1	(0.1)
Iron Deficiency Anaemia	2	(0.4)	0	(0.0)	2	(0.3)
Leukopenia	0	(0.0)	1	(0.4)	1	(0.1)
Lymphadenopathy	17	(3.4)	8	(2.8)	25	(3.2)
Neutropenia	5	(1.0)	4	(1.4)	9	(1.1)
Splenomegaly	0	(0.0)	1	(0.4)	1	(0.1)
Thrombocytopenia	1	(0.2)	0	(0.0)	1	(0.1)
Cardiac Disorders	12	(2.4)	10	(3.5)	22	(2.8)
Angina Pectoris	2	(0.4)	3	(1.1)	5	(0.6)
Arrhythmia	0	(0.0)	1	(0.4)	1	(0.1)
Cardiac Failure Congestive	2	(0.4)	0	(0.0)	2	(0.3)
Cardiomyopathy	0	(0.0)	1	(0.4)	1	(0.1)
Cardiovascular Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Coronary Artery Disease	2	(0.4)	1	(0.4)	3	(0.4)
Mitral Valve Incompetence	0	(0.0)	1	(0.4)	1	(0.1)
Myocardial Infarction	2	(0.4)	2	(0.7)	4	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Cardiac Disorders	12	(2.4)	10	(3.5)	22	(2.8)
Palpitations	2	(0.4)	0	(0.0)	2	(0.3)
Pericarditis	1	(0.2)	0	(0.0)	1	(0.1)
Sinus Tachycardia	0	(0.0)	1	(0.4)	1	(0.1)
Supraventricular Extrasystoles	0	(0.0)	1	(0.4)	1	(0.1)
Tachycardia	1	(0.2)	0	(0.0)	1	(0.1)
Ventricular Extrasystoles	1	(0.2)	0	(0.0)	1	(0.1)
Ventricular Tachycardia	0	(0.0)	1	(0.4)	1	(0.1)
Congenital, Familial And Genetic Disorders	1	(0.2)	2	(0.7)	3	(0.4)
Dermoid Cyst	0	(0.0)	1	(0.4)	1	(0.1)
Fanconi Syndrome	0	(0.0)	1	(0.4)	1	(0.1)
Hydrocele	1	(0.2)	0	(0.0)	1	(0.1)
Ear And Labyrinth Disorders	12	(2.4)	4	(1.4)	16	(2.0)
Auricular Swelling	1	(0.2)	0	(0.0)	1	(0.1)
Cerumen Impaction	3	(0.6)	0	(0.0)	3	(0.4)
Ear Pain	2	(0.4)	2	(0.7)	4	(0.5)
Hypoacusis	0	(0.0)	1	(0.4)	1	(0.1)
Tinnitus	2	(0.4)	1	(0.4)	3	(0.4)
Vertigo	5	(1.0)	1	(0.4)	6	(0.8)
Endocrine Disorders	3	(0.6)	1	(0.4)	4	(0.5)
Adrenal Insufficiency	1	(0.2)	1	(0.4)	2	(0.3)
Hyperthyroidism	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Endocrine Disorders	3	(0.6)	1	(0.4)	4	(0.5)
Hypogonadism	1	(0.2)	0	(0.0)	1	(0.1)
Eye Disorders	16	(3.2)	13	(4.6)	29	(3.7)
Blepharospasm	1	(0.2)	0	(0.0)	1	(0.1)
Blindness Transient	1	(0.2)	0	(0.0)	1	(0.1)
Cataract	1	(0.2)	0	(0.0)	1	(0.1)
Chalazion	0	(0.0)	1	(0.4)	1	(0.1)
Conjunctival Hyperaemia	0	(0.0)	1	(0.4)	1	(0.1)
Conjunctivitis	3	(0.6)	1	(0.4)	4	(0.5)
Diplopia	0	(0.0)	1	(0.4)	1	(0.1)
Dry Eye	1	(0.2)	1	(0.4)	2	(0.3)
Endophthalmitis	1	(0.2)	0	(0.0)	1	(0.1)
Eye Movement Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Eyelid Ptosis	1	(0.2)	0	(0.0)	1	(0.1)
Keratitis	0	(0.0)	1	(0.4)	1	(0.1)
Lacrimation Increased	0	(0.0)	1	(0.4)	1	(0.1)
Ocular Icterus	2	(0.4)	0	(0.0)	2	(0.3)
Photophobia	1	(0.2)	0	(0.0)	1	(0.1)
Retinal Detachment	1	(0.2)	0	(0.0)	1	(0.1)
Scotoma	0	(0.0)	1	(0.4)	1	(0.1)
Ulcerative Keratitis	0	(0.0)	1	(0.4)	1	(0.1)
Uveitis	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Eye Disorders	16	(3.2)	13	(4.6)	29	(3.7)
Vision Blurred	2	(0.4)	2	(0.7)	4	(0.5)
Visual Acuity Reduced	1	(0.2)	1	(0.4)	2	(0.3)
Visual Disturbance	1	(0.2)	1	(0.4)	2	(0.3)
Gastrointestinal Disorders	201	(39.6)	124	(44.0)	325	(41.2)
Abdominal Discomfort	3	(0.6)	4	(1.4)	7	(0.9)
Abdominal Distension	13	(2.6)	8	(2.8)	21	(2.7)
Abdominal Hernia	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Mass	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Pain	26	(5.1)	11	(3.9)	37	(4.7)
Abdominal Pain Lower	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Pain Upper	12	(2.4)	11	(3.9)	23	(2.9)
Anal Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Anal Fissure	0	(0.0)	1	(0.4)	1	(0.1)
Anal Fistula	0	(0.0)	1	(0.4)	1	(0.1)
Anal Ulcer	1	(0.2)	0	(0.0)	1	(0.1)
Anogenital Dysplasia	1	(0.2)	0	(0.0)	1	(0.1)
Aphthous Stomatitis	5	(1.0)	1	(0.4)	6	(0.8)
Barrett's Oesophagus	2	(0.4)	0	(0.0)	2	(0.3)
Bowel Sounds Abnormal	0	(0.0)	1	(0.4)	1	(0.1)
Breath Odour	1	(0.2)	0	(0.0)	1	(0.1)
Chapped Lips	2	(0.4)	1	(0.4)	3	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	201	(39.6)	124	(44.0)	325	(41.2)
Cheilitis	1	(0.2)	0	(0.0)	1	(0.1)
Colitis	1	(0.2)	0	(0.0)	1	(0.1)
Constipation	10	(2.0)	1	(0.4)	11	(1.4)
Defaecation Urgency	0	(0.0)	2	(0.7)	2	(0.3)
Dental Caries	2	(0.4)	0	(0.0)	2	(0.3)
Diarrhoea	84	(16.6)	55	(19.5)	139	(17.6)
Dry Mouth	2	(0.4)	3	(1.1)	5	(0.6)
Dyspepsia	8	(1.6)	5	(1.8)	13	(1.6)
Dysphagia	2	(0.4)	1	(0.4)	3	(0.4)
Eructation	2	(0.4)	1	(0.4)	3	(0.4)
Faeces Discoloured	0	(0.0)	1	(0.4)	1	(0.1)
Flatulence	15	(3.0)	9	(3.2)	24	(3.0)
Food Poisoning	0	(0.0)	1	(0.4)	1	(0.1)
Gastric Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Gastric Ulcer	1	(0.2)	0	(0.0)	1	(0.1)
Gastritis	6	(1.2)	3	(1.1)	9	(1.1)
Gastrointestinal Disorder	2	(0.4)	0	(0.0)	2	(0.3)
Gastrointestinal Haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)
Gastrointestinal Pain	2	(0.4)	0	(0.0)	2	(0.3)
Gastrooesophageal Reflux Disease	7	(1.4)	1	(0.4)	8	(1.0)
Gingival Pain	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	201	(39.6)	124	(44.0)	325	(41.2)
Gingivitis	2	(0.4)	0	(0.0)	2	(0.3)
Glossitis	1	(0.2)	0	(0.0)	1	(0.1)
Haematochezia	0	(0.0)	1	(0.4)	1	(0.1)
Haemorrhoids	4	(0.8)	4	(1.4)	8	(1.0)
Hypoaesthesia Oral	0	(0.0)	1	(0.4)	1	(0.1)
Inguinal Hernia	2	(0.4)	0	(0.0)	2	(0.3)
Irritable Bowel Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Leukoplakia Oral	0	(0.0)	1	(0.4)	1	(0.1)
Lip Dry	0	(0.0)	1	(0.4)	1	(0.1)
Malabsorption	1	(0.2)	0	(0.0)	1	(0.1)
Mouth Ulceration	3	(0.6)	2	(0.7)	5	(0.6)
Nausea	50	(9.9)	40	(14.2)	90	(11.4)
Odynophagia	1	(0.2)	1	(0.4)	2	(0.3)
Oesophageal Stenosis	1	(0.2)	0	(0.0)	1	(0.1)
Oral Mucosal Blistering	1	(0.2)	0	(0.0)	1	(0.1)
Oral Pain	2	(0.4)	0	(0.0)	2	(0.3)
Oral Soft Tissue Disorder	2	(0.4)	1	(0.4)	3	(0.4)
Palatal Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Pancreatitis	0	(0.0)	1	(0.4)	1	(0.1)
Pancreatitis Acute	1	(0.2)	0	(0.0)	1	(0.1)
Peptic Ulcer	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	201	(39.6)	124	(44.0)	325	(41.2)
Periodontitis	0	(0.0)	2	(0.7)	2	(0.3)
Proctitis	1	(0.2)	0	(0.0)	1	(0.1)
Pruritus Ani	1	(0.2)	2	(0.7)	3	(0.4)
Rectal Haemorrhage	3	(0.6)	1	(0.4)	4	(0.5)
Rectal Lesion	0	(0.0)	1	(0.4)	1	(0.1)
Rectal Stenosis	0	(0.0)	1	(0.4)	1	(0.1)
Reflux Oesophagitis	1	(0.2)	0	(0.0)	1	(0.1)
Salivary Hypersecretion	1	(0.2)	1	(0.4)	2	(0.3)
Sensitivity Of Teeth	1	(0.2)	0	(0.0)	1	(0.1)
Small Intestinal Obstruction	1	(0.2)	0	(0.0)	1	(0.1)
Stomach Discomfort	1	(0.2)	3	(1.1)	4	(0.5)
Stomatitis	1	(0.2)	1	(0.4)	2	(0.3)
Tongue Ulceration	1	(0.2)	0	(0.0)	1	(0.1)
Toothache	5	(1.0)	5	(1.8)	10	(1.3)
Upper Gastrointestinal Haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)
Varices Oesophageal	2	(0.4)	0	(0.0)	2	(0.3)
Vomiting	35	(6.9)	23	(8.2)	58	(7.4)
General Disorders And Administration Site Conditions	162	(32.0)	86	(30.5)	248	(31.4)
Asthenia	16	(3.2)	11	(3.9)	27	(3.4)
Chest Discomfort	4	(0.8)	1	(0.4)	5	(0.6)
Chest Pain	6	(1.2)	1	(0.4)	7	(0.9)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	162	(32.0)	86	(30.5)	248	(31.4)
Chills	3	(0.6)	2	(0.7)	5	(0.6)
Cyst	1	(0.2)	0	(0.0)	1	(0.1)
Drug Intolerance	0	(0.0)	1	(0.4)	1	(0.1)
Drug Withdrawal Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Facial Pain	1	(0.2)	0	(0.0)	1	(0.1)
Fatigue	40	(7.9)	13	(4.6)	53	(6.7)
Feeling Abnormal	1	(0.2)	2	(0.7)	3	(0.4)
Feeling Hot	1	(0.2)	0	(0.0)	1	(0.1)
Feeling Jittery	1	(0.2)	1	(0.4)	2	(0.3)
Induration	0	(0.0)	1	(0.4)	1	(0.1)
Inflammation	1	(0.2)	0	(0.0)	1	(0.1)
Influenza Like Illness	3	(0.6)	1	(0.4)	4	(0.5)
Injection Site Bruising	3	(0.6)	0	(0.0)	3	(0.4)
Injection Site Erythema	4	(0.8)	1	(0.4)	5	(0.6)
Injection Site Haemorrhage	2	(0.4)	0	(0.0)	2	(0.3)
Injection Site Induration	4	(0.8)	0	(0.0)	4	(0.5)
Injection Site Inflammation	1	(0.2)	1	(0.4)	2	(0.3)
Injection Site Irritation	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Nodule	5	(1.0)	5	(1.8)	10	(1.3)
Injection Site Pain	9	(1.8)	2	(0.7)	11	(1.4)
Injection Site Pruritus	1	(0.2)	1	(0.4)	2	(0.3)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	162	(32.0)	86	(30.5)	248	(31.4)
Injection Site Reaction	52	(10.3)	28	(9.9)	80	(10.1)
Injection Site Swelling	4	(0.8)	0	(0.0)	4	(0.5)
Irritability	2	(0.4)	0	(0.0)	2	(0.3)
Local Swelling	1	(0.2)	0	(0.0)	1	(0.1)
Malaise	3	(0.6)	2	(0.7)	5	(0.6)
Mass	1	(0.2)	1	(0.4)	2	(0.3)
Multi-Organ Failure	1	(0.2)	0	(0.0)	1	(0.1)
Nodule	3	(0.6)	1	(0.4)	4	(0.5)
Non-Cardiac Chest Pain	1	(0.2)	1	(0.4)	2	(0.3)
Oedema	1	(0.2)	2	(0.7)	3	(0.4)
Oedema Peripheral	7	(1.4)	4	(1.4)	11	(1.4)
Pain	1	(0.2)	4	(1.4)	5	(0.6)
Peripheral Coldness	0	(0.0)	1	(0.4)	1	(0.1)
Pitting Oedema	0	(0.0)	1	(0.4)	1	(0.1)
Pyrexia	25	(4.9)	29	(10.3)	54	(6.8)
Sensation Of Pressure	0	(0.0)	1	(0.4)	1	(0.1)
Swelling	2	(0.4)	0	(0.0)	2	(0.3)
Xerosis	2	(0.4)	0	(0.0)	2	(0.3)
Hepatobiliary Disorders	16	(3.2)	8	(2.8)	24	(3.0)
Cholangitis	1	(0.2)	0	(0.0)	1	(0.1)
Cholecystitis	1	(0.2)	1	(0.4)	2	(0.3)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Hepatobiliary Disorders	16	(3.2)	8	(2.8)	24	(3.0)
Cholelithiasis	2	(0.4)	1	(0.4)	3	(0.4)
Cholestasis	0	(0.0)	1	(0.4)	1	(0.1)
Gallbladder Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Gallbladder Polyp	1	(0.2)	0	(0.0)	1	(0.1)
Hepatic Pain	1	(0.2)	0	(0.0)	1	(0.1)
Hepatitis	3	(0.6)	1	(0.4)	4	(0.5)
Hepatitis Toxic	0	(0.0)	1	(0.4)	1	(0.1)
Hepatomegaly	1	(0.2)	3	(1.1)	4	(0.5)
Hyperbilirubinaemia	2	(0.4)	0	(0.0)	2	(0.3)
Jaundice	4	(0.8)	1	(0.4)	5	(0.6)
Portal Hypertension	1	(0.2)	0	(0.0)	1	(0.1)
Immune System Disorders	11	(2.2)	6	(2.1)	17	(2.2)
Allergy To Animal	0	(0.0)	1	(0.4)	1	(0.1)
Drug Hypersensitivity	2	(0.4)	1	(0.4)	3	(0.4)
Food Allergy	1	(0.2)	0	(0.0)	1	(0.1)
Hypersensitivity	3	(0.6)	3	(1.1)	6	(0.8)
Immune Reconstitution Syndrome	2	(0.4)	1	(0.4)	3	(0.4)
Seasonal Allergy	4	(0.8)	0	(0.0)	4	(0.5)
Infections And Infestations	240	(47.3)	136	(48.2)	376	(47.7)
AIDS Dementia Complex	0	(0.0)	1	(0.4)	1	(0.1)
Abscess	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	240	(47.3)	136	(48.2)	376	(47.7)
Abscess Bacterial	1	(0.2)	0	(0.0)	1	(0.1)
Abscess Limb	1	(0.2)	1	(0.4)	2	(0.3)
Acarodermatitis	1	(0.2)	1	(0.4)	2	(0.3)
Acinetobacter Bacteraemia	1	(0.2)	0	(0.0)	1	(0.1)
Acute Sinusitis	2	(0.4)	0	(0.0)	2	(0.3)
Anal Candidiasis	0	(0.0)	1	(0.4)	1	(0.1)
Anogenital Warts	11	(2.2)	4	(1.4)	15	(1.9)
Appendicitis	1	(0.2)	1	(0.4)	2	(0.3)
Ascariasis	1	(0.2)	0	(0.0)	1	(0.1)
Aspergillosis	1	(0.2)	0	(0.0)	1	(0.1)
Atypical Mycobacterial Lymphadenitis	0	(0.0)	1	(0.4)	1	(0.1)
Bacterial Toxaemia	1	(0.2)	0	(0.0)	1	(0.1)
Body Tinea	1	(0.2)	0	(0.0)	1	(0.1)
Bronchitis	17	(3.4)	10	(3.5)	27	(3.4)
Bronchitis Acute	5	(1.0)	4	(1.4)	9	(1.1)
Bronchitis Bacterial	0	(0.0)	1	(0.4)	1	(0.1)
Bronchitis Viral	0	(0.0)	1	(0.4)	1	(0.1)
Bronchopneumonia	1	(0.2)	0	(0.0)	1	(0.1)
Candidiasis	3	(0.6)	1	(0.4)	4	(0.5)
Carbuncle	1	(0.2)	1	(0.4)	2	(0.3)
Cellulitis	9	(1.8)	4	(1.4)	13	(1.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	240	(47.3)	136	(48.2)	376	(47.7)
Choriomeningitis Lymphocytic	2	(0.4)	0	(0.0)	2	(0.3)
Chronic Sinusitis	1	(0.2)	1	(0.4)	2	(0.3)
Cystitis	2	(0.4)	2	(0.7)	4	(0.5)
Cytomegalovirus Chorioretinitis	2	(0.4)	2	(0.7)	4	(0.5)
Cytomegalovirus Colitis	1	(0.2)	1	(0.4)	2	(0.3)
Cytomegalovirus Infection	1	(0.2)	0	(0.0)	1	(0.1)
Cytomegalovirus Viraemia	0	(0.0)	1	(0.4)	1	(0.1)
Dermatitis Infected	1	(0.2)	0	(0.0)	1	(0.1)
Diarrhoea Infectious	1	(0.2)	0	(0.0)	1	(0.1)
Ear Infection	1	(0.2)	3	(1.1)	4	(0.5)
Ecthyma	1	(0.2)	0	(0.0)	1	(0.1)
Endocarditis	0	(0.0)	1	(0.4)	1	(0.1)
Enterococcal Infection	0	(0.0)	1	(0.4)	1	(0.1)
Enterovirus Infection	0	(0.0)	1	(0.4)	1	(0.1)
Erythema Infectiosum	0	(0.0)	1	(0.4)	1	(0.1)
Eye Infection	1	(0.2)	0	(0.0)	1	(0.1)
Folliculitis	11	(2.2)	2	(0.7)	13	(1.6)
Fungal Infection	2	(0.4)	0	(0.0)	2	(0.3)
Fungal Skin Infection	0	(0.0)	2	(0.7)	2	(0.3)
Furuncle	4	(0.8)	4	(1.4)	8	(1.0)
Gastroenteritis	14	(2.8)	5	(1.8)	19	(2.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	240	(47.3)	136	(48.2)	376	(47.7)
Gastroenteritis Cryptosporidial	1	(0.2)	2	(0.7)	3	(0.4)
Gastroenteritis Rotavirus	0	(0.0)	1	(0.4)	1	(0.1)
Gastroenteritis Salmonella	0	(0.0)	1	(0.4)	1	(0.1)
Gastroenteritis Viral	1	(0.2)	0	(0.0)	1	(0.1)
Genital Candidiasis	1	(0.2)	0	(0.0)	1	(0.1)
Giardiasis	0	(0.0)	1	(0.4)	1	(0.1)
Groin Abscess	1	(0.2)	0	(0.0)	1	(0.1)
HIV Infection	1	(0.2)	0	(0.0)	1	(0.1)
HIV Wasting Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Helicobacter Gastritis	1	(0.2)	0	(0.0)	1	(0.1)
Helicobacter Infection	2	(0.4)	0	(0.0)	2	(0.3)
Hepatitis C	0	(0.0)	2	(0.7)	2	(0.3)
Herpes Oesophagitis	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Simplex	20	(3.9)	12	(4.3)	32	(4.1)
Herpes Virus Infection	3	(0.6)	2	(0.7)	5	(0.6)
Herpes Zoster	21	(4.1)	2	(0.7)	23	(2.9)
Hordeolum	1	(0.2)	1	(0.4)	2	(0.3)
Impetigo	2	(0.4)	1	(0.4)	3	(0.4)
Infection	1	(0.2)	0	(0.0)	1	(0.1)
Influenza	15	(3.0)	5	(1.8)	20	(2.5)
Laryngitis	2	(0.4)	1	(0.4)	3	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	240	(47.3)	136	(48.2)	376	(47.7)
Lower Respiratory Tract Infection	2	(0.4)	0	(0.0)	2	(0.3)
Lung Infection	2	(0.4)	0	(0.0)	2	(0.3)
Lymphangitis	1	(0.2)	0	(0.0)	1	(0.1)
Meningitis Cryptococcal	2	(0.4)	0	(0.0)	2	(0.3)
Molluscum Contagiosum	2	(0.4)	2	(0.7)	4	(0.5)
Mycobacterial Infection	1	(0.2)	0	(0.0)	1	(0.1)
Nasopharyngitis	31	(6.1)	11	(3.9)	42	(5.3)
Oesophageal Candidiasis	3	(0.6)	6	(2.1)	9	(1.1)
Onychomycosis	4	(0.8)	5	(1.8)	9	(1.1)
Oral Candidiasis	6	(1.2)	15	(5.3)	21	(2.7)
Oral Fungal Infection	1	(0.2)	0	(0.0)	1	(0.1)
Oral Hairy Leukoplakia	1	(0.2)	0	(0.0)	1	(0.1)
Oropharyngeal Candidiasis	2	(0.4)	2	(0.7)	4	(0.5)
Otitis Externa	3	(0.6)	0	(0.0)	3	(0.4)
Otitis Media	2	(0.4)	2	(0.7)	4	(0.5)
Otitis Media Acute	1	(0.2)	0	(0.0)	1	(0.1)
Papilloma Viral Infection	4	(0.8)	0	(0.0)	4	(0.5)
Paronychia	1	(0.2)	0	(0.0)	1	(0.1)
Parotitis	0	(0.0)	1	(0.4)	1	(0.1)
Penile Infection	0	(0.0)	1	(0.4)	1	(0.1)
Pharyngeal Candidiasis	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	240	(47.3)	136	(48.2)	376	(47.7)
Pharyngitis	7	(1.4)	2	(0.7)	9	(1.1)
Pharyngitis Streptococcal	2	(0.4)	0	(0.0)	2	(0.3)
Pneumonia	11	(2.2)	7	(2.5)	18	(2.3)
Pneumonia Bacterial	1	(0.2)	0	(0.0)	1	(0.1)
Pneumonia Pneumococcal	1	(0.2)	0	(0.0)	1	(0.1)
Postoperative Wound Infection	0	(0.0)	1	(0.4)	1	(0.1)
Proctitis Herpes	0	(0.0)	2	(0.7)	2	(0.3)
Progressive Multifocal Leukoencephalopathy	1	(0.2)	0	(0.0)	1	(0.1)
Pseudomonal Sepsis	0	(0.0)	1	(0.4)	1	(0.1)
Respiratory Tract Infection	8	(1.6)	2	(0.7)	10	(1.3)
Respiratory Tract Infection Viral	4	(0.8)	0	(0.0)	4	(0.5)
Retroviral Infection	1	(0.2)	0	(0.0)	1	(0.1)
Rhinitis	5	(1.0)	3	(1.1)	8	(1.0)
Salmonella Bacteraemia	0	(0.0)	1	(0.4)	1	(0.1)
Septic Shock	2	(0.4)	1	(0.4)	3	(0.4)
Sinusitis	16	(3.2)	7	(2.5)	23	(2.9)
Skin Infection	2	(0.4)	1	(0.4)	3	(0.4)
Spirochaetal Infection	1	(0.2)	0	(0.0)	1	(0.1)
Staphylococcal Bacteraemia	1	(0.2)	0	(0.0)	1	(0.1)
Staphylococcal Infection	4	(0.8)	0	(0.0)	4	(0.5)
Strongyloidiasis	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	240	(47.3)	136	(48.2)	376	(47.7)
Subcutaneous Abscess	2	(0.4)	4	(1.4)	6	(0.8)
Syphilis	2	(0.4)	0	(0.0)	2	(0.3)
Tinea Cruris	2	(0.4)	1	(0.4)	3	(0.4)
Tinea Infection	0	(0.0)	1	(0.4)	1	(0.1)
Tinea Pedis	2	(0.4)	1	(0.4)	3	(0.4)
Tinea Versicolour	1	(0.2)	1	(0.4)	2	(0.3)
Tonsillitis	2	(0.4)	0	(0.0)	2	(0.3)
Tonsillitis Streptococcal	1	(0.2)	0	(0.0)	1	(0.1)
Tooth Abscess	3	(0.6)	0	(0.0)	3	(0.4)
Tooth Infection	0	(0.0)	5	(1.8)	5	(0.6)
Tracheobronchitis	0	(0.0)	1	(0.4)	1	(0.1)
Tuberculosis	1	(0.2)	0	(0.0)	1	(0.1)
Upper Respiratory Tract Infection	27	(5.3)	16	(5.7)	43	(5.4)
Urethritis	1	(0.2)	1	(0.4)	2	(0.3)
Urinary Tract Infection	6	(1.2)	6	(2.1)	12	(1.5)
Urinary Tract Infection Enterococcal	1	(0.2)	0	(0.0)	1	(0.1)
Vaginal Candidiasis	1	(0.2)	2	(0.7)	3	(0.4)
Vaginal Infection	1	(0.2)	0	(0.0)	1	(0.1)
Vaginitis Bacterial	0	(0.0)	2	(0.7)	2	(0.3)
Viral Infection	5	(1.0)	2	(0.7)	7	(0.9)
Viral Labyrinthitis	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	240	(47.3)	136	(48.2)	376	(47.7)
Viral Pharyngitis	1	(0.2)	0	(0.0)	1	(0.1)
Viral Rhinitis	1	(0.2)	0	(0.0)	1	(0.1)
Viral Upper Respiratory Tract Infection	1	(0.2)	0	(0.0)	1	(0.1)
Injury, Poisoning And Procedural Complications	36	(7.1)	15	(5.3)	51	(6.5)
Accidental Overdose	1	(0.2)	0	(0.0)	1	(0.1)
Animal Bite	2	(0.4)	0	(0.0)	2	(0.3)
Arthropod Bite	4	(0.8)	1	(0.4)	5	(0.6)
Contusion	5	(1.0)	1	(0.4)	6	(0.8)
Drug Toxicity	1	(0.2)	0	(0.0)	1	(0.1)
Fibula Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Gun Shot Wound	0	(0.0)	1	(0.4)	1	(0.1)
Hand Fracture	2	(0.4)	0	(0.0)	2	(0.3)
Hip Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Humerus Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Incision Site Complication	2	(0.4)	1	(0.4)	3	(0.4)
Incisional Hernia	1	(0.2)	0	(0.0)	1	(0.1)
Intentional Overdose	1	(0.2)	1	(0.4)	2	(0.3)
Joint Injury	1	(0.2)	0	(0.0)	1	(0.1)
Joint Sprain	0	(0.0)	1	(0.4)	1	(0.1)
Limb Injury	1	(0.2)	1	(0.4)	2	(0.3)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Injury, Poisoning And Procedural Complications	36	(7.1)	15	(5.3)	51	(6.5)
Lower Limb Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Meniscus Lesion	1	(0.2)	0	(0.0)	1	(0.1)
Mucosal Excoriation	1	(0.2)	0	(0.0)	1	(0.1)
Muscle Strain	1	(0.2)	0	(0.0)	1	(0.1)
Nerve Injury	1	(0.2)	0	(0.0)	1	(0.1)
Overdose	1	(0.2)	0	(0.0)	1	(0.1)
Post Concussion Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Post Procedural Haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)
Post-Traumatic Pain	1	(0.2)	0	(0.0)	1	(0.1)
Rib Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Scratch	0	(0.0)	1	(0.4)	1	(0.1)
Skeletal Injury	0	(0.0)	1	(0.4)	1	(0.1)
Skin Laceration	1	(0.2)	1	(0.4)	2	(0.3)
Spinal Fracture	1	(0.2)	1	(0.4)	2	(0.3)
Thermal Burn	1	(0.2)	0	(0.0)	1	(0.1)
Thoracic Vertebral Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Tibia Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Tooth Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Tooth Injury	1	(0.2)	0	(0.0)	1	(0.1)
Wrist Fracture	2	(0.4)	0	(0.0)	2	(0.3)
Investigations	16	(3.2)	15	(5.3)	31	(3.9)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Investigations	16	(3.2)	15	(5.3)	31	(3.9)
Arterial Bruit	0	(0.0)	1	(0.4)	1	(0.1)
Bacteria Stool Identified	1	(0.2)	0	(0.0)	1	(0.1)
Blood Cholesterol Increased	1	(0.2)	0	(0.0)	1	(0.1)
Blood Pressure Increased	2	(0.4)	1	(0.4)	3	(0.4)
Blood Testosterone Decreased	0	(0.0)	1	(0.4)	1	(0.1)
Body Temperature Increased	0	(0.0)	1	(0.4)	1	(0.1)
Breath Sounds Abnormal	1	(0.2)	0	(0.0)	1	(0.1)
Cardiac Murmur	0	(0.0)	1	(0.4)	1	(0.1)
Electrocardiogram PR Prolongation	1	(0.2)	0	(0.0)	1	(0.1)
Electrocardiogram QT Prolonged	1	(0.2)	0	(0.0)	1	(0.1)
Lymph Node Palpable	1	(0.2)	2	(0.7)	3	(0.4)
Weight Decreased	5	(1.0)	7	(2.5)	12	(1.5)
Weight Increased	5	(1.0)	1	(0.4)	6	(0.8)
Metabolism And Nutrition Disorders	52	(10.3)	24	(8.5)	76	(9.6)
Anorexia	11	(2.2)	6	(2.1)	17	(2.2)
Central Obesity	1	(0.2)	0	(0.0)	1	(0.1)
Decreased Appetite	8	(1.6)	4	(1.4)	12	(1.5)
Dehydration	4	(0.8)	1	(0.4)	5	(0.6)
Diabetes Mellitus	5	(1.0)	2	(0.7)	7	(0.9)
Diabetes Mellitus Inadequate Control	1	(0.2)	0	(0.0)	1	(0.1)
Diabetes Mellitus Non-Insulin-Dependent	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	52	(10.3)	24	(8.5)	76	(9.6)
Dyslipidaemia	3	(0.6)	0	(0.0)	3	(0.4)
Facial Wasting	1	(0.2)	0	(0.0)	1	(0.1)
Gout	3	(0.6)	0	(0.0)	3	(0.4)
Hypercholesterolaemia	3	(0.6)	3	(1.1)	6	(0.8)
Hyperglycaemia	2	(0.4)	1	(0.4)	3	(0.4)
Hyperkalaemia	0	(0.0)	1	(0.4)	1	(0.1)
Hyperlactacidaemia	3	(0.6)	0	(0.0)	3	(0.4)
Hyperlipidaemia	4	(0.8)	1	(0.4)	5	(0.6)
Hypertriglyceridaemia	2	(0.4)	3	(1.1)	5	(0.6)
Hypoalbuminaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hypoglycaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hypokalaemia	1	(0.2)	0	(0.0)	1	(0.1)
Increased Appetite	2	(0.4)	0	(0.0)	2	(0.3)
Lipomatosis	3	(0.6)	0	(0.0)	3	(0.4)
Malnutrition	0	(0.0)	1	(0.4)	1	(0.1)
Metabolic Acidosis	1	(0.2)	0	(0.0)	1	(0.1)
Obesity	1	(0.2)	0	(0.0)	1	(0.1)
Musculoskeletal And Connective Tissue Disorders	77	(15.2)	38	(13.5)	115	(14.6)
Arthralgia	14	(2.8)	7	(2.5)	21	(2.7)
Back Pain	10	(2.0)	7	(2.5)	17	(2.2)
Bone Pain	1	(0.2)	1	(0.4)	2	(0.3)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	77	(15.2)	38	(13.5)	115	(14.6)
Bursitis	4	(0.8)	0	(0.0)	4	(0.5)
Buttock Pain	1	(0.2)	0	(0.0)	1	(0.1)
Exostosis	0	(0.0)	1	(0.4)	1	(0.1)
Groin Pain	2	(0.4)	0	(0.0)	2	(0.3)
Intervertebral Disc Protrusion	0	(0.0)	1	(0.4)	1	(0.1)
Joint Stiffness	0	(0.0)	1	(0.4)	1	(0.1)
Joint Swelling	3	(0.6)	0	(0.0)	3	(0.4)
Muscle Atrophy	2	(0.4)	0	(0.0)	2	(0.3)
Muscle Hypertrophy	0	(0.0)	1	(0.4)	1	(0.1)
Muscle Spasms	8	(1.6)	7	(2.5)	15	(1.9)
Muscle Twitching	1	(0.2)	0	(0.0)	1	(0.1)
Muscular Weakness	3	(0.6)	0	(0.0)	3	(0.4)
Musculoskeletal Chest Pain	5	(1.0)	0	(0.0)	5	(0.6)
Musculoskeletal Pain	4	(0.8)	1	(0.4)	5	(0.6)
Musculoskeletal Stiffness	0	(0.0)	1	(0.4)	1	(0.1)
Myalgia	10	(2.0)	7	(2.5)	17	(2.2)
Myositis	2	(0.4)	0	(0.0)	2	(0.3)
Neck Pain	3	(0.6)	1	(0.4)	4	(0.5)
Nodule On Extremity	1	(0.2)	0	(0.0)	1	(0.1)
Osteoarthritis	2	(0.4)	0	(0.0)	2	(0.3)
Osteoporosis	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	77	(15.2)	38	(13.5)	115	(14.6)
Osteoporotic Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Pain In Extremity	16	(3.2)	7	(2.5)	23	(2.9)
Spinal Osteoarthritis	2	(0.4)	0	(0.0)	2	(0.3)
Tendon Pain	0	(0.0)	1	(0.4)	1	(0.1)
Tendonitis	5	(1.0)	1	(0.4)	6	(0.8)
Tenosynovitis	0	(0.0)	1	(0.4)	1	(0.1)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	22	(4.3)	9	(3.2)	31	(3.9)
Acrochordon	0	(0.0)	1	(0.4)	1	(0.1)
B-Cell Lymphoma	1	(0.2)	0	(0.0)	1	(0.1)
Fibrous Histiocytoma	0	(0.0)	1	(0.4)	1	(0.1)
Hepatic Neoplasm Malignant	1	(0.2)	0	(0.0)	1	(0.1)
Kaposi's Sarcoma AIDS Related	2	(0.4)	0	(0.0)	2	(0.3)
Lipoma	1	(0.2)	0	(0.0)	1	(0.1)
Lymphoma	1	(0.2)	0	(0.0)	1	(0.1)
Metastatic Squamous Cell Carcinoma	1	(0.2)	0	(0.0)	1	(0.1)
Rectal Cancer	1	(0.2)	0	(0.0)	1	(0.1)
Rectal Cancer Stage 0	1	(0.2)	0	(0.0)	1	(0.1)
Seborrhoeic Keratosis	1	(0.2)	0	(0.0)	1	(0.1)
Skin Papilloma	10	(2.0)	7	(2.5)	17	(2.2)
Squamous Cell Carcinoma	2	(0.4)	0	(0.0)	2	(0.3)
T-Cell Lymphoma	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Nervous System Disorders	112	(22.1)	64	(22.7)	176	(22.3)
Ageusia	0	(0.0)	1	(0.4)	1	(0.1)
Allodynia	2	(0.4)	0	(0.0)	2	(0.3)
Amnesia	3	(0.6)	1	(0.4)	4	(0.5)
Aphonia	1	(0.2)	0	(0.0)	1	(0.1)
Areflexia	1	(0.2)	0	(0.0)	1	(0.1)
Balance Disorder	0	(0.0)	2	(0.7)	2	(0.3)
Brachial Plexopathy	1	(0.2)	0	(0.0)	1	(0.1)
Bradykinesia	1	(0.2)	0	(0.0)	1	(0.1)
Carpal Tunnel Syndrome	3	(0.6)	0	(0.0)	3	(0.4)
Convulsion	2	(0.4)	1	(0.4)	3	(0.4)
Dizziness	20	(3.9)	6	(2.1)	26	(3.3)
Dizziness Postural	2	(0.4)	0	(0.0)	2	(0.3)
Dysarthria	1	(0.2)	0	(0.0)	1	(0.1)
Dysgeusia	5	(1.0)	4	(1.4)	9	(1.1)
Dysphasia	0	(0.0)	1	(0.4)	1	(0.1)
Encephalitis	1	(0.2)	0	(0.0)	1	(0.1)
Encephalopathy	1	(0.2)	0	(0.0)	1	(0.1)
Epilepsy	0	(0.0)	1	(0.4)	1	(0.1)
Headache	49	(9.7)	33	(11.7)	82	(10.4)
Hypersomnia	1	(0.2)	0	(0.0)	1	(0.1)
Hypoaesthesia	4	(0.8)	3	(1.1)	7	(0.9)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Nervous System Disorders	112	(22.1)	64	(22.7)	176	(22.3)
Lacunar Infarction	0	(0.0)	1	(0.4)	1	(0.1)
Lethargy	2	(0.4)	0	(0.0)	2	(0.3)
Migraine	4	(0.8)	2	(0.7)	6	(0.8)
Neuralgia	5	(1.0)	0	(0.0)	5	(0.6)
Neuropathy	3	(0.6)	4	(1.4)	7	(0.9)
Neuropathy Peripheral	5	(1.0)	4	(1.4)	9	(1.1)
Paraesthesia	6	(1.2)	5	(1.8)	11	(1.4)
Parosmia	0	(0.0)	1	(0.4)	1	(0.1)
Polyneuropathy	1	(0.2)	0	(0.0)	1	(0.1)
Poor Quality Sleep	0	(0.0)	1	(0.4)	1	(0.1)
Post Herpetic Neuralgia	2	(0.4)	0	(0.0)	2	(0.3)
Presyncope	1	(0.2)	0	(0.0)	1	(0.1)
Psychomotor Hyperactivity	0	(0.0)	1	(0.4)	1	(0.1)
Radiculopathy	1	(0.2)	0	(0.0)	1	(0.1)
Sciatica	1	(0.2)	0	(0.0)	1	(0.1)
Somnolence	5	(1.0)	4	(1.4)	9	(1.1)
Speech Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Syncope	3	(0.6)	1	(0.4)	4	(0.5)
Syncope Vasovagal	1	(0.2)	0	(0.0)	1	(0.1)
Tension Headache	1	(0.2)	0	(0.0)	1	(0.1)
Transient Ischaemic Attack	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Nervous System Disorders	112	(22.1)	64	(22.7)	176	(22.3)
Tremor	2	(0.4)	1	(0.4)	3	(0.4)
Psychiatric Disorders	55	(10.8)	34	(12.1)	89	(11.3)
Abnormal Dreams	4	(0.8)	3	(1.1)	7	(0.9)
Adjustment Disorder With Depressed Mood	1	(0.2)	0	(0.0)	1	(0.1)
Anxiety	9	(1.8)	4	(1.4)	13	(1.6)
Attention Deficit/Hyperactivity Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Depressed Mood	1	(0.2)	1	(0.4)	2	(0.3)
Depression	13	(2.6)	8	(2.8)	21	(2.7)
Impatience	0	(0.0)	1	(0.4)	1	(0.1)
Initial Insomnia	0	(0.0)	1	(0.4)	1	(0.1)
Insomnia	20	(3.9)	10	(3.5)	30	(3.8)
Libido Decreased	1	(0.2)	1	(0.4)	2	(0.3)
Mental Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Mental Status Changes	1	(0.2)	1	(0.4)	2	(0.3)
Middle Insomnia	1	(0.2)	0	(0.0)	1	(0.1)
Obsessive Thoughts	1	(0.2)	0	(0.0)	1	(0.1)
Panic Attack	2	(0.4)	1	(0.4)	3	(0.4)
Restlessness	0	(0.0)	1	(0.4)	1	(0.1)
Sleep Disorder	3	(0.6)	4	(1.4)	7	(0.9)
Stress	3	(0.6)	0	(0.0)	3	(0.4)
Renal And Urinary Disorders	24	(4.7)	14	(5.0)	38	(4.8)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Renal And Urinary Disorders	24	(4.7)	14	(5.0)	38	(4.8)
Bladder Pain	0	(0.0)	1	(0.4)	1	(0.1)
Costovertebral Angle Tenderness	1	(0.2)	0	(0.0)	1	(0.1)
Dysuria	1	(0.2)	5	(1.8)	6	(0.8)
Focal Glomerulosclerosis	2	(0.4)	0	(0.0)	2	(0.3)
Glycosuria	1	(0.2)	0	(0.0)	1	(0.1)
Haematuria	1	(0.2)	1	(0.4)	2	(0.3)
Hypertonic Bladder	1	(0.2)	0	(0.0)	1	(0.1)
Nephrolithiasis	0	(0.0)	3	(1.1)	3	(0.4)
Nephropathy	1	(0.2)	1	(0.4)	2	(0.3)
Nephropathy Toxic	1	(0.2)	0	(0.0)	1	(0.1)
Nephrotic Syndrome	2	(0.4)	0	(0.0)	2	(0.3)
Nocturia	4	(0.8)	1	(0.4)	5	(0.6)
Pollakiuria	2	(0.4)	1	(0.4)	3	(0.4)
Polyuria	1	(0.2)	0	(0.0)	1	(0.1)
Proteinuria	1	(0.2)	0	(0.0)	1	(0.1)
Renal Cyst	1	(0.2)	2	(0.7)	3	(0.4)
Renal Failure	1	(0.2)	1	(0.4)	2	(0.3)
Renal Failure Acute	0	(0.0)	2	(0.7)	2	(0.3)
Renal Failure Chronic	1	(0.2)	0	(0.0)	1	(0.1)
Renal Impairment	1	(0.2)	0	(0.0)	1	(0.1)
Renal Pain	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Renal And Urinary Disorders	24	(4.7)	14	(5.0)	38	(4.8)
Renal Tubular Necrosis	1	(0.2)	0	(0.0)	1	(0.1)
Urinary Hesitation	1	(0.2)	0	(0.0)	1	(0.1)
Urinary Incontinence	1	(0.2)	0	(0.0)	1	(0.1)
Urinary Retention	1	(0.2)	1	(0.4)	2	(0.3)
Urinary Tract Obstruction	1	(0.2)	0	(0.0)	1	(0.1)
Reproductive System And Breast Disorders	27	(5.3)	7	(2.5)	34	(4.3)
Benign Prostatic Hyperplasia	1	(0.2)	0	(0.0)	1	(0.1)
Breast Swelling	1	(0.2)	0	(0.0)	1	(0.1)
Cervical Dysplasia	1	(0.2)	1	(0.4)	2	(0.3)
Ejaculation Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Epididymitis	1	(0.2)	0	(0.0)	1	(0.1)
Erectile Dysfunction	6	(1.2)	1	(0.4)	7	(0.9)
Genital Lesion	1	(0.2)	0	(0.0)	1	(0.1)
Genital Pruritus Female	1	(0.2)	0	(0.0)	1	(0.1)
Genital Ulceration	1	(0.2)	0	(0.0)	1	(0.1)
Gynaecomastia	3	(0.6)	1	(0.4)	4	(0.5)
Menopausal Symptoms	1	(0.2)	0	(0.0)	1	(0.1)
Menstruation Irregular	0	(0.0)	1	(0.4)	1	(0.1)
Metrorrhagia	1	(0.2)	0	(0.0)	1	(0.1)
Oedema Genital	0	(0.0)	1	(0.4)	1	(0.1)
Ovarian Cyst	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Reproductive System And Breast Disorders	27	(5.3)	7	(2.5)	34	(4.3)
Pelvic Pain	1	(0.2)	0	(0.0)	1	(0.1)
Prostatic Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Prostatitis	4	(0.8)	0	(0.0)	4	(0.5)
Scrotal Oedema	1	(0.2)	0	(0.0)	1	(0.1)
Scrotal Pain	0	(0.0)	1	(0.4)	1	(0.1)
Testicular Swelling	1	(0.2)	0	(0.0)	1	(0.1)
Vaginal Discharge	1	(0.2)	0	(0.0)	1	(0.1)
Respiratory, Thoracic And Mediastinal Disorders	64	(12.6)	35	(12.4)	99	(12.5)
Asthma	5	(1.0)	2	(0.7)	7	(0.9)
Bronchopneumopathy	1	(0.2)	0	(0.0)	1	(0.1)
Bronchospasm	1	(0.2)	1	(0.4)	2	(0.3)
Chronic Obstructive Pulmonary Disease	1	(0.2)	0	(0.0)	1	(0.1)
Cough	24	(4.7)	8	(2.8)	32	(4.1)
Dysphonia	3	(0.6)	0	(0.0)	3	(0.4)
Dyspnoea	3	(0.6)	3	(1.1)	6	(0.8)
Dyspnoea Exertional	1	(0.2)	2	(0.7)	3	(0.4)
Epistaxis	4	(0.8)	0	(0.0)	4	(0.5)
Hypoxia	0	(0.0)	1	(0.4)	1	(0.1)
Increased Upper Airway Secretion	1	(0.2)	0	(0.0)	1	(0.1)
Interstitial Lung Disease	1	(0.2)	1	(0.4)	2	(0.3)
Nasal Congestion	7	(1.4)	1	(0.4)	8	(1.0)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Respiratory, Thoracic And Mediastinal Disorders	64	(12.6)	35	(12.4)	99	(12.5)
Paranasal Sinus Hypersecretion	2	(0.4)	1	(0.4)	3	(0.4)
Pharyngeal Erythema	2	(0.4)	1	(0.4)	3	(0.4)
Pharyngeal Inflammation	2	(0.4)	0	(0.0)	2	(0.3)
Pharyngolaryngeal Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Pharyngolaryngeal Pain	9	(1.8)	11	(3.9)	20	(2.5)
Pleural Effusion	1	(0.2)	0	(0.0)	1	(0.1)
Postnasal Drip	0	(0.0)	2	(0.7)	2	(0.3)
Productive Cough	3	(0.6)	1	(0.4)	4	(0.5)
Pulmonary Granuloma	1	(0.2)	0	(0.0)	1	(0.1)
Pulmonary Hypertension	0	(0.0)	1	(0.4)	1	(0.1)
Respiratory Disorder	2	(0.4)	0	(0.0)	2	(0.3)
Rhinitis Allergic	0	(0.0)	2	(0.7)	2	(0.3)
Rhinitis Seasonal	0	(0.0)	1	(0.4)	1	(0.1)
Rhinorrhoea	2	(0.4)	1	(0.4)	3	(0.4)
Sinus Congestion	3	(0.6)	5	(1.8)	8	(1.0)
Sinus Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Sleep Apnoea Syndrome	1	(0.2)	1	(0.4)	2	(0.3)
Sneezing	0	(0.0)	1	(0.4)	1	(0.1)
Snoring	1	(0.2)	0	(0.0)	1	(0.1)
Tonsillar Ulcer	1	(0.2)	0	(0.0)	1	(0.1)
Wheezing	3	(0.6)	0	(0.0)	3	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	119	(23.5)	57	(20.2)	176	(22.3)
Acne	5	(1.0)	0	(0.0)	5	(0.6)
Acrodermatitis	1	(0.2)	0	(0.0)	1	(0.1)
Actinic Keratosis	0	(0.0)	1	(0.4)	1	(0.1)
Alopecia	2	(0.4)	1	(0.4)	3	(0.4)
Alopecia Effluvium	0	(0.0)	1	(0.4)	1	(0.1)
Blister	1	(0.2)	2	(0.7)	3	(0.4)
Dermal Cyst	1	(0.2)	3	(1.1)	4	(0.5)
Dermatitis	3	(0.6)	0	(0.0)	3	(0.4)
Dermatitis Acneiform	1	(0.2)	0	(0.0)	1	(0.1)
Dermatitis Allergic	1	(0.2)	0	(0.0)	1	(0.1)
Dermatitis Atopic	1	(0.2)	0	(0.0)	1	(0.1)
Dermatitis Contact	2	(0.4)	0	(0.0)	2	(0.3)
Dry Skin	3	(0.6)	4	(1.4)	7	(0.9)
Dyshidrosis	1	(0.2)	1	(0.4)	2	(0.3)
Ecchymosis	2	(0.4)	0	(0.0)	2	(0.3)
Eczema	3	(0.6)	6	(2.1)	9	(1.1)
Erythema	6	(1.2)	1	(0.4)	7	(0.9)
Exfoliative Rash	0	(0.0)	1	(0.4)	1	(0.1)
Hyperhidrosis	8	(1.6)	2	(0.7)	10	(1.3)
Hyperkeratosis	0	(0.0)	1	(0.4)	1	(0.1)
Hypoaesthesia Facial	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	119	(23.5)	57	(20.2)	176	(22.3)
Lipoatrophy	1	(0.2)	1	(0.4)	2	(0.3)
Lipodystrophy Acquired	7	(1.4)	2	(0.7)	9	(1.1)
Lipohypertrophy	3	(0.6)	1	(0.4)	4	(0.5)
Nail Discolouration	1	(0.2)	0	(0.0)	1	(0.1)
Neurodermatitis	1	(0.2)	0	(0.0)	1	(0.1)
Night Sweats	12	(2.4)	8	(2.8)	20	(2.5)
Palmar Erythema	0	(0.0)	1	(0.4)	1	(0.1)
Penile Ulceration	1	(0.2)	0	(0.0)	1	(0.1)
Photosensitivity Reaction	1	(0.2)	0	(0.0)	1	(0.1)
Pigmentation Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Pityriasis	1	(0.2)	0	(0.0)	1	(0.1)
Pityriasis Rosea	1	(0.2)	0	(0.0)	1	(0.1)
Prurigo	2	(0.4)	0	(0.0)	2	(0.3)
Pruritus	14	(2.8)	6	(2.1)	20	(2.5)
Pruritus Generalised	3	(0.6)	1	(0.4)	4	(0.5)
Psoriasis	1	(0.2)	0	(0.0)	1	(0.1)
Rash	27	(5.3)	7	(2.5)	34	(4.3)
Rash Follicular	1	(0.2)	0	(0.0)	1	(0.1)
Rash Generalised	1	(0.2)	0	(0.0)	1	(0.1)
Rash Macular	3	(0.6)	1	(0.4)	4	(0.5)
Rash Maculo-Papular	4	(0.8)	1	(0.4)	5	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	119	(23.5)	57	(20.2)	176	(22.3)
Rash Papular	3	(0.6)	2	(0.7)	5	(0.6)
Rash Pruritic	2	(0.4)	0	(0.0)	2	(0.3)
Rosacea	2	(0.4)	0	(0.0)	2	(0.3)
Seborrhoeic Dermatitis	4	(0.8)	3	(1.1)	7	(0.9)
Skin Hyperpigmentation	1	(0.2)	1	(0.4)	2	(0.3)
Skin Irritation	0	(0.0)	1	(0.4)	1	(0.1)
Skin Lesion	6	(1.2)	0	(0.0)	6	(0.8)
Skin Nodule	2	(0.4)	3	(1.1)	5	(0.6)
Skin Ulcer	0	(0.0)	1	(0.4)	1	(0.1)
Stasis Dermatitis	1	(0.2)	0	(0.0)	1	(0.1)
Subcutaneous Nodule	4	(0.8)	4	(1.4)	8	(1.0)
Swelling Face	2	(0.4)	1	(0.4)	3	(0.4)
Systemic Lupus Erythematosus Rash	0	(0.0)	1	(0.4)	1	(0.1)
Urticaria	1	(0.2)	0	(0.0)	1	(0.1)
Xeroderma	2	(0.4)	0	(0.0)	2	(0.3)
Social Circumstances	0	(0.0)	1	(0.4)	1	(0.1)
Drug Abuser	0	(0.0)	1	(0.4)	1	(0.1)
Vascular Disorders	23	(4.5)	10	(3.5)	33	(4.2)
Deep Vein Thrombosis	1	(0.2)	0	(0.0)	1	(0.1)
Flushing	1	(0.2)	0	(0.0)	1	(0.1)
Haematoma	2	(0.4)	3	(1.1)	5	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Vascular Disorders	23	(4.5)	10	(3.5)	33	(4.2)
Hot Flush	1	(0.2)	0	(0.0)	1	(0.1)
Hyperaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hypertension	13	(2.6)	4	(1.4)	17	(2.2)
Hypotension	1	(0.2)	2	(0.7)	3	(0.4)
Infarction	0	(0.0)	1	(0.4)	1	(0.1)
Shock	1	(0.2)	0	(0.0)	1	(0.1)
Thrombophlebitis	1	(0.2)	0	(0.0)	1	(0.1)
Varicophlebitis	0	(0.0)	1	(0.4)	1	(0.1)
Venous Thrombosis	1	(0.2)	0	(0.0)	1	(0.1)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005-Define, P018-Define, P019-Define]

Appendix 2.7.4: 18

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	411	(81.1)	238	(84.4)	649	(82.3)
Patients With No Adverse Experience	96	(18.9)	44	(15.6)	140	(17.7)
Blood And Lymphatic System Disorders	31	(6.1)	19	(6.7)	50	(6.3)
Anaemia	10	(2.0)	8	(2.8)	18	(2.3)
Anaemia Macrocytic	1	(0.2)	0	(0.0)	1	(0.1)
Iron Deficiency Anaemia	2	(0.4)	0	(0.0)	2	(0.3)
Leukopenia	0	(0.0)	1	(0.4)	1	(0.1)
Lymphadenopathy	15	(3.0)	8	(2.8)	23	(2.9)
Neutropenia	5	(1.0)	3	(1.1)	8	(1.0)
Thrombocytopenia	1	(0.2)	0	(0.0)	1	(0.1)
Cardiac Disorders	8	(1.6)	8	(2.8)	16	(2.0)
Angina Pectoris	0	(0.0)	3	(1.1)	3	(0.4)
Arrhythmia	0	(0.0)	1	(0.4)	1	(0.1)
Cardiac Failure Congestive	2	(0.4)	0	(0.0)	2	(0.3)
Cardiomyopathy	0	(0.0)	1	(0.4)	1	(0.1)
Cardiovascular Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Coronary Artery Disease	1	(0.2)	1	(0.4)	2	(0.3)
Mitral Valve Incompetence	0	(0.0)	1	(0.4)	1	(0.1)
Myocardial Infarction	1	(0.2)	1	(0.4)	2	(0.3)
Palpitations	1	(0.2)	0	(0.0)	1	(0.1)
Pericarditis	1	(0.2)	0	(0.0)	1	(0.1)
Sinus Tachycardia	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Cardiac Disorders	8	(1.6)	8	(2.8)	16	(2.0)
Tachycardia	1	(0.2)	0	(0.0)	1	(0.1)
Ventricular Extrasystoles	1	(0.2)	0	(0.0)	1	(0.1)
Congenital, Familial And Genetic Disorders	1	(0.2)	2	(0.7)	3	(0.4)
Dermoid Cyst	0	(0.0)	1	(0.4)	1	(0.1)
Hydrocele	1	(0.2)	0	(0.0)	1	(0.1)
Preternatural Anus	0	(0.0)	1	(0.4)	1	(0.1)
Ear And Labyrinth Disorders	11	(2.2)	4	(1.4)	15	(1.9)
Auricular Swelling	1	(0.2)	0	(0.0)	1	(0.1)
Cerumen Impaction	3	(0.6)	0	(0.0)	3	(0.4)
Ear Pain	2	(0.4)	2	(0.7)	4	(0.5)
Hypoacusis	0	(0.0)	1	(0.4)	1	(0.1)
Tinnitus	2	(0.4)	1	(0.4)	3	(0.4)
Vertigo	4	(0.8)	1	(0.4)	5	(0.6)
Endocrine Disorders	2	(0.4)	1	(0.4)	3	(0.4)
Adrenal Insufficiency	1	(0.2)	1	(0.4)	2	(0.3)
Hyperthyroidism	1	(0.2)	0	(0.0)	1	(0.1)
Eye Disorders	14	(2.8)	12	(4.3)	26	(3.3)
Blepharospasm	1	(0.2)	0	(0.0)	1	(0.1)
Blindness Transient	1	(0.2)	0	(0.0)	1	(0.1)
Cataract	1	(0.2)	0	(0.0)	1	(0.1)
Chalazion	0	(0.0)	1	(0.4)	1	(0.1)
Conjunctival Hyperaemia	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Eye Disorders	14	(2.8)	12	(4.3)	26	(3.3)
Conjunctivitis	3	(0.6)	1	(0.4)	4	(0.5)
Diplopia	0	(0.0)	1	(0.4)	1	(0.1)
Endophthalmitis	1	(0.2)	0	(0.0)	1	(0.1)
Eye Movement Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Lacrimation Increased	0	(0.0)	1	(0.4)	1	(0.1)
Ocular Icterus	2	(0.4)	0	(0.0)	2	(0.3)
Photophobia	1	(0.2)	0	(0.0)	1	(0.1)
Retinal Detachment	1	(0.2)	0	(0.0)	1	(0.1)
Scotoma	0	(0.0)	1	(0.4)	1	(0.1)
Ulcerative Keratitis	0	(0.0)	1	(0.4)	1	(0.1)
Uveitis	0	(0.0)	1	(0.4)	1	(0.1)
Vision Blurred	1	(0.2)	2	(0.7)	3	(0.4)
Visual Acuity Reduced	1	(0.2)	1	(0.4)	2	(0.3)
Visual Disturbance	1	(0.2)	1	(0.4)	2	(0.3)
Gastrointestinal Disorders	191	(37.7)	122	(43.3)	313	(39.7)
Abdominal Discomfort	3	(0.6)	2	(0.7)	5	(0.6)
Abdominal Distension	11	(2.2)	8	(2.8)	19	(2.4)
Abdominal Hernia	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Mass	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Pain	23	(4.5)	10	(3.5)	33	(4.2)
Abdominal Pain Lower	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Pain Upper	11	(2.2)	10	(3.5)	21	(2.7)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	191	(37.7)	122	(43.3)	313	(39.7)
Anal Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Anal Fissure	0	(0.0)	1	(0.4)	1	(0.1)
Anal Fistula	0	(0.0)	1	(0.4)	1	(0.1)
Anal Ulcer	1	(0.2)	0	(0.0)	1	(0.1)
Anogenital Dysplasia	1	(0.2)	0	(0.0)	1	(0.1)
Aphthous Stomatitis	5	(1.0)	1	(0.4)	6	(0.8)
Barrett's Oesophagus	2	(0.4)	0	(0.0)	2	(0.3)
Bowel Sounds Abnormal	0	(0.0)	1	(0.4)	1	(0.1)
Breath Odour	1	(0.2)	0	(0.0)	1	(0.1)
Chapped Lips	1	(0.2)	1	(0.4)	2	(0.3)
Colitis	1	(0.2)	0	(0.0)	1	(0.1)
Constipation	9	(1.8)	1	(0.4)	10	(1.3)
Defaecation Urgency	0	(0.0)	2	(0.7)	2	(0.3)
Dental Caries	2	(0.4)	0	(0.0)	2	(0.3)
Diarrhoea	79	(15.6)	54	(19.1)	133	(16.9)
Dry Mouth	2	(0.4)	3	(1.1)	5	(0.6)
Dyspepsia	7	(1.4)	5	(1.8)	12	(1.5)
Dysphagia	2	(0.4)	1	(0.4)	3	(0.4)
Eructation	2	(0.4)	1	(0.4)	3	(0.4)
Faeces Discoloured	0	(0.0)	1	(0.4)	1	(0.1)
Flatulence	13	(2.6)	9	(3.2)	22	(2.8)
Food Poisoning	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	191	(37.7)	122	(43.3)	313	(39.7)
Gastric Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Gastric Ulcer	1	(0.2)	0	(0.0)	1	(0.1)
Gastritis	4	(0.8)	3	(1.1)	7	(0.9)
Gastrointestinal Disorder	2	(0.4)	0	(0.0)	2	(0.3)
Gastrointestinal Haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)
Gastrointestinal Pain	2	(0.4)	0	(0.0)	2	(0.3)
Gastrooesophageal Reflux Disease	6	(1.2)	1	(0.4)	7	(0.9)
Gingival Pain	1	(0.2)	0	(0.0)	1	(0.1)
Gingivitis	1	(0.2)	0	(0.0)	1	(0.1)
Glossitis	2	(0.4)	0	(0.0)	2	(0.3)
Haematochezia	0	(0.0)	1	(0.4)	1	(0.1)
Haemorrhoids	3	(0.6)	4	(1.4)	7	(0.9)
Hypoaesthesia Oral	0	(0.0)	1	(0.4)	1	(0.1)
Inguinal Hernia	1	(0.2)	0	(0.0)	1	(0.1)
Irritable Bowel Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Leukoplakia Oral	0	(0.0)	1	(0.4)	1	(0.1)
Lip Dry	0	(0.0)	1	(0.4)	1	(0.1)
Malabsorption	1	(0.2)	0	(0.0)	1	(0.1)
Mouth Ulceration	3	(0.6)	2	(0.7)	5	(0.6)
Nausea	48	(9.5)	37	(13.1)	85	(10.8)
Odynophagia	1	(0.2)	1	(0.4)	2	(0.3)
Oesophageal Stenosis	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	191	(37.7)	122	(43.3)	313	(39.7)
Oral Pain	2	(0.4)	0	(0.0)	2	(0.3)
Oral Soft Tissue Disorder	2	(0.4)	1	(0.4)	3	(0.4)
Pancreatitis	0	(0.0)	1	(0.4)	1	(0.1)
Pancreatitis Acute	1	(0.2)	0	(0.0)	1	(0.1)
Peptic Ulcer	1	(0.2)	0	(0.0)	1	(0.1)
Periodontitis	0	(0.0)	2	(0.7)	2	(0.3)
Pruritus Ani	1	(0.2)	2	(0.7)	3	(0.4)
Rectal Haemorrhage	3	(0.6)	1	(0.4)	4	(0.5)
Rectal Lesion	0	(0.0)	1	(0.4)	1	(0.1)
Rectal Stenosis	0	(0.0)	1	(0.4)	1	(0.1)
Reflux Oesophagitis	1	(0.2)	0	(0.0)	1	(0.1)
Salivary Hypersecretion	0	(0.0)	1	(0.4)	1	(0.1)
Sensitivity Of Teeth	1	(0.2)	0	(0.0)	1	(0.1)
Small Intestinal Obstruction	1	(0.2)	0	(0.0)	1	(0.1)
Stomach Discomfort	1	(0.2)	3	(1.1)	4	(0.5)
Stomatitis	1	(0.2)	1	(0.4)	2	(0.3)
Tongue Ulceration	1	(0.2)	0	(0.0)	1	(0.1)
Tooth Disorder	1	(0.2)	1	(0.4)	2	(0.3)
Toothache	4	(0.8)	3	(1.1)	7	(0.9)
Upper Gastrointestinal Haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)
Varices Oesophageal	1	(0.2)	0	(0.0)	1	(0.1)
Vomiting	34	(6.7)	21	(7.4)	55	(7.0)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	150	(29.6)	80	(28.4)	230	(29.2)
Asthenia	14	(2.8)	11	(3.9)	25	(3.2)
Chest Discomfort	4	(0.8)	1	(0.4)	5	(0.6)
Chest Pain	6	(1.2)	2	(0.7)	8	(1.0)
Chills	3	(0.6)	2	(0.7)	5	(0.6)
Cyst	1	(0.2)	0	(0.0)	1	(0.1)
Drug Intolerance	0	(0.0)	1	(0.4)	1	(0.1)
Drug Withdrawal Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Facial Pain	1	(0.2)	0	(0.0)	1	(0.1)
Fatigue	36	(7.1)	11	(3.9)	47	(6.0)
Feeling Abnormal	1	(0.2)	2	(0.7)	3	(0.4)
Feeling Hot	1	(0.2)	0	(0.0)	1	(0.1)
Feeling Jittery	1	(0.2)	1	(0.4)	2	(0.3)
Inflammation	1	(0.2)	0	(0.0)	1	(0.1)
Influenza Like Illness	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Bruising	3	(0.6)	0	(0.0)	3	(0.4)
Injection Site Erythema	3	(0.6)	1	(0.4)	4	(0.5)
Injection Site Haemorrhage	2	(0.4)	0	(0.0)	2	(0.3)
Injection Site Induration	4	(0.8)	0	(0.0)	4	(0.5)
Injection Site Inflammation	1	(0.2)	1	(0.4)	2	(0.3)
Injection Site Irritation	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Nodule	5	(1.0)	4	(1.4)	9	(1.1)
Injection Site Pain	7	(1.4)	1	(0.4)	8	(1.0)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	150	(29.6)	80	(28.4)	230	(29.2)
Injection Site Pruritus	1	(0.2)	1	(0.4)	2	(0.3)
Injection Site Reaction	47	(9.3)	27	(9.6)	74	(9.4)
Injection Site Swelling	4	(0.8)	0	(0.0)	4	(0.5)
Irritability	2	(0.4)	0	(0.0)	2	(0.3)
Local Swelling	1	(0.2)	0	(0.0)	1	(0.1)
Malaise	2	(0.4)	2	(0.7)	4	(0.5)
Mass	1	(0.2)	1	(0.4)	2	(0.3)
Mucosal Inflammation	1	(0.2)	0	(0.0)	1	(0.1)
Multi-Organ Failure	1	(0.2)	0	(0.0)	1	(0.1)
Nodule	1	(0.2)	1	(0.4)	2	(0.3)
Non-Cardiac Chest Pain	0	(0.0)	1	(0.4)	1	(0.1)
Oedema	1	(0.2)	2	(0.7)	3	(0.4)
Oedema Peripheral	7	(1.4)	3	(1.1)	10	(1.3)
Pain	1	(0.2)	1	(0.4)	2	(0.3)
Peripheral Coldness	0	(0.0)	1	(0.4)	1	(0.1)
Pitting Oedema	0	(0.0)	1	(0.4)	1	(0.1)
Pyrexia	22	(4.3)	27	(9.6)	49	(6.2)
Sensation Of Pressure	0	(0.0)	1	(0.4)	1	(0.1)
Swelling	2	(0.4)	0	(0.0)	2	(0.3)
Xerosis	2	(0.4)	0	(0.0)	2	(0.3)
Hepatobiliary Disorders	11	(2.2)	6	(2.1)	17	(2.2)
Cholangitis	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Hepatobiliary Disorders	11	(2.2)	6	(2.1)	17	(2.2)
Cholecystitis	1	(0.2)	1	(0.4)	2	(0.3)
Cholelithiasis	1	(0.2)	1	(0.4)	2	(0.3)
Cholestasis	0	(0.0)	1	(0.4)	1	(0.1)
Gallbladder Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Hepatic Pain	1	(0.2)	0	(0.0)	1	(0.1)
Hepatitis	3	(0.6)	1	(0.4)	4	(0.5)
Hepatomegaly	1	(0.2)	2	(0.7)	3	(0.4)
Jaundice	4	(0.8)	1	(0.4)	5	(0.6)
Immune System Disorders	10	(2.0)	5	(1.8)	15	(1.9)
Allergy To Animal	0	(0.0)	1	(0.4)	1	(0.1)
Drug Hypersensitivity	2	(0.4)	1	(0.4)	3	(0.4)
Hypersensitivity	3	(0.6)	3	(1.1)	6	(0.8)
Immune Reconstitution Syndrome	2	(0.4)	0	(0.0)	2	(0.3)
Seasonal Allergy	4	(0.8)	0	(0.0)	4	(0.5)
Infections And Infestations	205	(40.4)	122	(43.3)	327	(41.4)
AIDS Dementia Complex	0	(0.0)	1	(0.4)	1	(0.1)
Abscess	0	(0.0)	1	(0.4)	1	(0.1)
Abscess Bacterial	1	(0.2)	0	(0.0)	1	(0.1)
Abscess Limb	1	(0.2)	1	(0.4)	2	(0.3)
Acarodermatitis	1	(0.2)	1	(0.4)	2	(0.3)
Acinetobacter Bacteraemia	1	(0.2)	0	(0.0)	1	(0.1)
Acute HIV Infection	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	205	(40.4)	122	(43.3)	327	(41.4)
Acute Sinusitis	1	(0.2)	0	(0.0)	1	(0.1)
Anogenital Warts	8	(1.6)	3	(1.1)	11	(1.4)
Bacterial Toxaemia	1	(0.2)	0	(0.0)	1	(0.1)
Body Tinea	1	(0.2)	0	(0.0)	1	(0.1)
Bronchitis	10	(2.0)	9	(3.2)	19	(2.4)
Bronchitis Acute	5	(1.0)	3	(1.1)	8	(1.0)
Bronchitis Bacterial	0	(0.0)	1	(0.4)	1	(0.1)
Bronchitis Viral	0	(0.0)	1	(0.4)	1	(0.1)
Bronchopneumonia	1	(0.2)	0	(0.0)	1	(0.1)
Bronchopulmonary Aspergillosis	1	(0.2)	0	(0.0)	1	(0.1)
Candidiasis	3	(0.6)	1	(0.4)	4	(0.5)
Carbuncle	1	(0.2)	1	(0.4)	2	(0.3)
Cellulitis	9	(1.8)	4	(1.4)	13	(1.6)
Chronic Sinusitis	1	(0.2)	1	(0.4)	2	(0.3)
Clostridial Infection	1	(0.2)	0	(0.0)	1	(0.1)
Cystitis	2	(0.4)	2	(0.7)	4	(0.5)
Cytomegalovirus Chorioretinitis	2	(0.4)	2	(0.7)	4	(0.5)
Cytomegalovirus Colitis	1	(0.2)	1	(0.4)	2	(0.3)
Cytomegalovirus Infection	1	(0.2)	0	(0.0)	1	(0.1)
Cytomegalovirus Viraemia	0	(0.0)	1	(0.4)	1	(0.1)
Ear Infection	1	(0.2)	2	(0.7)	3	(0.4)
Ecthyma	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	205	(40.4)	122	(43.3)	327	(41.4)
Enterococcal Infection	0	(0.0)	1	(0.4)	1	(0.1)
Enterovirus Infection	0	(0.0)	1	(0.4)	1	(0.1)
Erythema Induratum	0	(0.0)	1	(0.4)	1	(0.1)
Erythema Infectiosum	0	(0.0)	1	(0.4)	1	(0.1)
Eye Infection	1	(0.2)	0	(0.0)	1	(0.1)
Folliculitis	11	(2.2)	1	(0.4)	12	(1.5)
Fungal Infection	2	(0.4)	1	(0.4)	3	(0.4)
Fungal Skin Infection	0	(0.0)	1	(0.4)	1	(0.1)
Furuncle	4	(0.8)	2	(0.7)	6	(0.8)
Gastroenteritis	9	(1.8)	3	(1.1)	12	(1.5)
Gastroenteritis Cryptosporidial	0	(0.0)	2	(0.7)	2	(0.3)
Gastroenteritis Rotavirus	0	(0.0)	1	(0.4)	1	(0.1)
Gastroenteritis Salmonella	0	(0.0)	1	(0.4)	1	(0.1)
Gastroenteritis Viral	1	(0.2)	0	(0.0)	1	(0.1)
Genital Candidiasis	1	(0.2)	0	(0.0)	1	(0.1)
Giardiasis	0	(0.0)	1	(0.4)	1	(0.1)
Groin Abscess	1	(0.2)	0	(0.0)	1	(0.1)
Helicobacter Gastritis	1	(0.2)	0	(0.0)	1	(0.1)
Helicobacter Infection	1	(0.2)	0	(0.0)	1	(0.1)
Hepatitis C	0	(0.0)	1	(0.4)	1	(0.1)
Herpes Oesophagitis	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Simplex	17	(3.4)	12	(4.3)	29	(3.7)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	205	(40.4)	122	(43.3)	327	(41.4)
Herpes Virus Infection	3	(0.6)	1	(0.4)	4	(0.5)
Herpes Zoster	17	(3.4)	2	(0.7)	19	(2.4)
Hordeolum	0	(0.0)	1	(0.4)	1	(0.1)
Impetigo	2	(0.4)	1	(0.4)	3	(0.4)
Infection	1	(0.2)	0	(0.0)	1	(0.1)
Influenza	10	(2.0)	4	(1.4)	14	(1.8)
Laryngitis	2	(0.4)	1	(0.4)	3	(0.4)
Localised Infection	0	(0.0)	1	(0.4)	1	(0.1)
Lower Respiratory Tract Infection	2	(0.4)	0	(0.0)	2	(0.3)
Lung Infection	2	(0.4)	0	(0.0)	2	(0.3)
Lymphangitis	1	(0.2)	0	(0.0)	1	(0.1)
Meningitis	2	(0.4)	0	(0.0)	2	(0.3)
Meningitis Cryptococcal	2	(0.4)	0	(0.0)	2	(0.3)
Molluscum Contagiosum	2	(0.4)	2	(0.7)	4	(0.5)
Mycobacterial Infection	1	(0.2)	0	(0.0)	1	(0.1)
Mycobacterium Avium Complex Infection	0	(0.0)	1	(0.4)	1	(0.1)
Nasopharyngitis	25	(4.9)	10	(3.5)	35	(4.4)
Nipple Infection	1	(0.2)	0	(0.0)	1	(0.1)
Oesophageal Candidiasis	3	(0.6)	6	(2.1)	9	(1.1)
Onychomycosis	4	(0.8)	5	(1.8)	9	(1.1)
Oral Candidiasis	7	(1.4)	13	(4.6)	20	(2.5)
Oropharyngeal Candidiasis	2	(0.4)	2	(0.7)	4	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	205	(40.4)	122	(43.3)	327	(41.4)
Otitis Externa	3	(0.6)	0	(0.0)	3	(0.4)
Otitis Media	2	(0.4)	2	(0.7)	4	(0.5)
Otitis Media Acute	1	(0.2)	0	(0.0)	1	(0.1)
Papilloma Viral Infection	2	(0.4)	1	(0.4)	3	(0.4)
Paronychia	1	(0.2)	0	(0.0)	1	(0.1)
Parotitis	0	(0.0)	1	(0.4)	1	(0.1)
Pharyngeal Candidiasis	1	(0.2)	0	(0.0)	1	(0.1)
Pharyngitis	6	(1.2)	2	(0.7)	8	(1.0)
Pharyngitis Streptococcal	1	(0.2)	0	(0.0)	1	(0.1)
Pneumonia	9	(1.8)	6	(2.1)	15	(1.9)
Pneumonia Bacterial	1	(0.2)	0	(0.0)	1	(0.1)
Pneumonia Pneumococcal	1	(0.2)	0	(0.0)	1	(0.1)
Proctitis Herpes	0	(0.0)	1	(0.4)	1	(0.1)
Progressive Multifocal Leukoencephalopathy	1	(0.2)	0	(0.0)	1	(0.1)
Pseudomonal Sepsis	0	(0.0)	1	(0.4)	1	(0.1)
Pulmonary Tuberculosis	1	(0.2)	0	(0.0)	1	(0.1)
Pulpitis Dental	1	(0.2)	0	(0.0)	1	(0.1)
Respiratory Tract Infection	6	(1.2)	2	(0.7)	8	(1.0)
Respiratory Tract Infection Viral	3	(0.6)	0	(0.0)	3	(0.4)
Rhinitis	4	(0.8)	3	(1.1)	7	(0.9)
Salmonella Bacteraemia	0	(0.0)	1	(0.4)	1	(0.1)
Septic Shock	2	(0.4)	1	(0.4)	3	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	205	(40.4)	122	(43.3)	327	(41.4)
Sinusitis	15	(3.0)	7	(2.5)	22	(2.8)
Skin Infection	1	(0.2)	1	(0.4)	2	(0.3)
Spirochaetal Infection	1	(0.2)	0	(0.0)	1	(0.1)
Staphylococcal Bacteraemia	1	(0.2)	0	(0.0)	1	(0.1)
Staphylococcal Infection	3	(0.6)	0	(0.0)	3	(0.4)
Strongyloidiasis	0	(0.0)	1	(0.4)	1	(0.1)
Subcutaneous Abscess	2	(0.4)	3	(1.1)	5	(0.6)
Syphilis	2	(0.4)	0	(0.0)	2	(0.3)
Tinea Cruris	1	(0.2)	0	(0.0)	1	(0.1)
Tinea Infection	0	(0.0)	1	(0.4)	1	(0.1)
Tinea Pedis	1	(0.2)	1	(0.4)	2	(0.3)
Tinea Versicolour	1	(0.2)	0	(0.0)	1	(0.1)
Tonsillitis	1	(0.2)	0	(0.0)	1	(0.1)
Tonsillitis Streptococcal	1	(0.2)	0	(0.0)	1	(0.1)
Tooth Abscess	3	(0.6)	0	(0.0)	3	(0.4)
Tooth Infection	0	(0.0)	4	(1.4)	4	(0.5)
Tracheobronchitis	0	(0.0)	1	(0.4)	1	(0.1)
Upper Respiratory Tract Infection	21	(4.1)	13	(4.6)	34	(4.3)
Ureteritis	0	(0.0)	1	(0.4)	1	(0.1)
Urethritis	1	(0.2)	0	(0.0)	1	(0.1)
Urinary Tract Infection	5	(1.0)	4	(1.4)	9	(1.1)
Urinary Tract Infection Enterococcal	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	205	(40.4)	122	(43.3)	327	(41.4)
Vaginal Candidiasis	1	(0.2)	2	(0.7)	3	(0.4)
Vaginitis Bacterial	0	(0.0)	2	(0.7)	2	(0.3)
Viral Infection	3	(0.6)	1	(0.4)	4	(0.5)
Viral Labyrinthitis	1	(0.2)	0	(0.0)	1	(0.1)
Viral Pharyngitis	1	(0.2)	0	(0.0)	1	(0.1)
Viral Rhinitis	1	(0.2)	0	(0.0)	1	(0.1)
Injury, Poisoning And Procedural Complications	25	(4.9)	9	(3.2)	34	(4.3)
Animal Bite	1	(0.2)	0	(0.0)	1	(0.1)
Arthropod Bite	2	(0.4)	1	(0.4)	3	(0.4)
Contusion	4	(0.8)	1	(0.4)	5	(0.6)
Drug Toxicity	1	(0.2)	0	(0.0)	1	(0.1)
Fibula Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Gun Shot Wound	0	(0.0)	1	(0.4)	1	(0.1)
Hand Fracture	2	(0.4)	0	(0.0)	2	(0.3)
Hip Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Humerus Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Incision Site Complication	1	(0.2)	0	(0.0)	1	(0.1)
Incisional Hernia	1	(0.2)	0	(0.0)	1	(0.1)
Intentional Overdose	1	(0.2)	0	(0.0)	1	(0.1)
Limb Injury	1	(0.2)	1	(0.4)	2	(0.3)
Lower Limb Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Mucosal Excoriation	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Injury, Poisoning And Procedural Complications	25	(4.9)	9	(3.2)	34	(4.3)
Muscle Strain	1	(0.2)	0	(0.0)	1	(0.1)
Nerve Injury	1	(0.2)	0	(0.0)	1	(0.1)
Overdose	1	(0.2)	0	(0.0)	1	(0.1)
Post Concussion Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Post Procedural Haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)
Skin Laceration	0	(0.0)	1	(0.4)	1	(0.1)
Spinal Fracture	1	(0.2)	0	(0.0)	1	(0.1)
Thermal Burn	1	(0.2)	0	(0.0)	1	(0.1)
Thoracic Vertebral Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Tibia Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Tooth Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Tooth Injury	1	(0.2)	0	(0.0)	1	(0.1)
Wrist Fracture	2	(0.4)	0	(0.0)	2	(0.3)
Investigations	12	(2.4)	15	(5.3)	27	(3.4)
Arterial Bruit	0	(0.0)	1	(0.4)	1	(0.1)
Blood Pressure Increased	2	(0.4)	1	(0.4)	3	(0.4)
Blood Testosterone Decreased	0	(0.0)	1	(0.4)	1	(0.1)
Body Temperature Increased	0	(0.0)	1	(0.4)	1	(0.1)
Breath Sounds Abnormal	1	(0.2)	0	(0.0)	1	(0.1)
Cardiac Murmur	0	(0.0)	1	(0.4)	1	(0.1)
Electrocardiogram PR Prolongation	1	(0.2)	0	(0.0)	1	(0.1)
Lymph Node Palpable	1	(0.2)	2	(0.7)	3	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Investigations	12	(2.4)	15	(5.3)	27	(3.4)
Weight Decreased	5	(1.0)	7	(2.5)	12	(1.5)
Weight Increased	4	(0.8)	1	(0.4)	5	(0.6)
Metabolism And Nutrition Disorders	43	(8.5)	21	(7.4)	64	(8.1)
Anorexia	7	(1.4)	6	(2.1)	13	(1.6)
Body Fat Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Cachexia	1	(0.2)	0	(0.0)	1	(0.1)
Central Obesity	1	(0.2)	0	(0.0)	1	(0.1)
Decreased Appetite	7	(1.4)	4	(1.4)	11	(1.4)
Dehydration	4	(0.8)	0	(0.0)	4	(0.5)
Diabetes Mellitus	5	(1.0)	3	(1.1)	8	(1.0)
Diabetes Mellitus Inadequate Control	1	(0.2)	0	(0.0)	1	(0.1)
Dyslipidaemia	2	(0.4)	0	(0.0)	2	(0.3)
Facial Wasting	1	(0.2)	0	(0.0)	1	(0.1)
Gout	3	(0.6)	0	(0.0)	3	(0.4)
Hypercholesterolaemia	2	(0.4)	2	(0.7)	4	(0.5)
Hyperglycaemia	1	(0.2)	1	(0.4)	2	(0.3)
Hyperkalaemia	0	(0.0)	1	(0.4)	1	(0.1)
Hyperlactacidaemia	3	(0.6)	0	(0.0)	3	(0.4)
Hyperlipidaemia	2	(0.4)	1	(0.4)	3	(0.4)
Hypertriglyceridaemia	2	(0.4)	3	(1.1)	5	(0.6)
Hypoalbuminaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hypoglycaemia	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	43	(8.5)	21	(7.4)	64	(8.1)
Hypokalaemia	1	(0.2)	0	(0.0)	1	(0.1)
Increased Appetite	2	(0.4)	0	(0.0)	2	(0.3)
Lipomatosis	2	(0.4)	0	(0.0)	2	(0.3)
Metabolic Acidosis	1	(0.2)	0	(0.0)	1	(0.1)
Obesity	1	(0.2)	0	(0.0)	1	(0.1)
Musculoskeletal And Connective Tissue Disorders	65	(12.8)	34	(12.1)	99	(12.5)
Arthralgia	12	(2.4)	7	(2.5)	19	(2.4)
Back Pain	9	(1.8)	7	(2.5)	16	(2.0)
Bone Pain	1	(0.2)	1	(0.4)	2	(0.3)
Bursitis	3	(0.6)	0	(0.0)	3	(0.4)
Buttock Pain	3	(0.6)	0	(0.0)	3	(0.4)
Groin Pain	1	(0.2)	0	(0.0)	1	(0.1)
Intervertebral Disc Protrusion	0	(0.0)	1	(0.4)	1	(0.1)
Joint Swelling	3	(0.6)	0	(0.0)	3	(0.4)
Muscle Atrophy	1	(0.2)	0	(0.0)	1	(0.1)
Muscle Hypertrophy	0	(0.0)	1	(0.4)	1	(0.1)
Muscle Spasms	6	(1.2)	8	(2.8)	14	(1.8)
Muscle Twitching	1	(0.2)	0	(0.0)	1	(0.1)
Muscular Weakness	3	(0.6)	0	(0.0)	3	(0.4)
Musculoskeletal Chest Pain	4	(0.8)	0	(0.0)	4	(0.5)
Musculoskeletal Pain	2	(0.4)	0	(0.0)	2	(0.3)
Myalgia	6	(1.2)	7	(2.5)	13	(1.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	65	(12.8)	34	(12.1)	99	(12.5)
Myositis	2	(0.4)	0	(0.0)	2	(0.3)
Neck Pain	2	(0.4)	1	(0.4)	3	(0.4)
Nodule On Extremity	1	(0.2)	0	(0.0)	1	(0.1)
Osteoarthritis	2	(0.4)	0	(0.0)	2	(0.3)
Osteoporosis	0	(0.0)	1	(0.4)	1	(0.1)
Osteoporotic Fracture	0	(0.0)	1	(0.4)	1	(0.1)
Pain In Extremity	15	(3.0)	4	(1.4)	19	(2.4)
Tendon Pain	1	(0.2)	0	(0.0)	1	(0.1)
Tendonitis	3	(0.6)	1	(0.4)	4	(0.5)
Tenosynovitis	0	(0.0)	1	(0.4)	1	(0.1)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	23	(4.5)	10	(3.5)	33	(4.2)
Acrochordon	1	(0.2)	2	(0.7)	3	(0.4)
Anal Cancer Stage 0	1	(0.2)	0	(0.0)	1	(0.1)
B-Cell Lymphoma	1	(0.2)	0	(0.0)	1	(0.1)
Fibrous Histiocytoma	0	(0.0)	1	(0.4)	1	(0.1)
Hepatic Neoplasm Malignant	1	(0.2)	0	(0.0)	1	(0.1)
Kaposi's Sarcoma	2	(0.4)	0	(0.0)	2	(0.3)
Lipoma	1	(0.2)	0	(0.0)	1	(0.1)
Lung Neoplasm	1	(0.2)	0	(0.0)	1	(0.1)
Lymphoma	2	(0.4)	0	(0.0)	2	(0.3)
Mycosis Fungoides	1	(0.2)	0	(0.0)	1	(0.1)
Rectal Cancer	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	23	(4.5)	10	(3.5)	33	(4.2)
Skin Papilloma	10	(2.0)	7	(2.5)	17	(2.2)
Squamous Cell Carcinoma	2	(0.4)	0	(0.0)	2	(0.3)
Nervous System Disorders	99	(19.5)	63	(22.3)	162	(20.5)
Ageusia	0	(0.0)	1	(0.4)	1	(0.1)
Allodynia	2	(0.4)	0	(0.0)	2	(0.3)
Amnesia	3	(0.6)	1	(0.4)	4	(0.5)
Aphonia	1	(0.2)	0	(0.0)	1	(0.1)
Areflexia	1	(0.2)	0	(0.0)	1	(0.1)
Balance Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Brachial Plexopathy	1	(0.2)	0	(0.0)	1	(0.1)
Carpal Tunnel Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Cervicobrachial Syndrome	0	(0.0)	1	(0.4)	1	(0.1)
Convulsion	1	(0.2)	1	(0.4)	2	(0.3)
Dizziness	19	(3.7)	6	(2.1)	25	(3.2)
Dizziness Postural	2	(0.4)	0	(0.0)	2	(0.3)
Dysgeusia	5	(1.0)	4	(1.4)	9	(1.1)
Dysphasia	0	(0.0)	1	(0.4)	1	(0.1)
Encephalitis	1	(0.2)	0	(0.0)	1	(0.1)
Encephalopathy	1	(0.2)	0	(0.0)	1	(0.1)
Epilepsy	0	(0.0)	1	(0.4)	1	(0.1)
Headache	44	(8.7)	33	(11.7)	77	(9.8)
Hypersomnia	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Nervous System Disorders	99	(19.5)	63	(22.3)	162	(20.5)
Hypoaesthesia	5	(1.0)	3	(1.1)	8	(1.0)
Lacunar Infarction	0	(0.0)	1	(0.4)	1	(0.1)
Lethargy	2	(0.4)	0	(0.0)	2	(0.3)
Migraine	1	(0.2)	3	(1.1)	4	(0.5)
Neuralgia	3	(0.6)	0	(0.0)	3	(0.4)
Neuropathy	2	(0.4)	2	(0.7)	4	(0.5)
Neuropathy Peripheral	4	(0.8)	4	(1.4)	8	(1.0)
Paraesthesia	5	(1.0)	5	(1.8)	10	(1.3)
Parosmia	0	(0.0)	1	(0.4)	1	(0.1)
Polyneuropathy	1	(0.2)	0	(0.0)	1	(0.1)
Post Herpetic Neuralgia	2	(0.4)	0	(0.0)	2	(0.3)
Presyncope	1	(0.2)	0	(0.0)	1	(0.1)
Psychomotor Hyperactivity	0	(0.0)	1	(0.4)	1	(0.1)
Radial Nerve Palsy	0	(0.0)	1	(0.4)	1	(0.1)
Radiculopathy	1	(0.2)	0	(0.0)	1	(0.1)
Sciatica	2	(0.4)	0	(0.0)	2	(0.3)
Somnolence	5	(1.0)	4	(1.4)	9	(1.1)
Speech Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Syncope	3	(0.6)	1	(0.4)	4	(0.5)
Tension Headache	1	(0.2)	0	(0.0)	1	(0.1)
Transient Ischaemic Attack	0	(0.0)	1	(0.4)	1	(0.1)
Tremor	2	(0.4)	1	(0.4)	3	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Psychiatric Disorders	45	(8.9)	30	(10.6)	75	(9.5)
Abnormal Dreams	3	(0.6)	3	(1.1)	6	(0.8)
Adjustment Disorder With Depressed Mood	1	(0.2)	0	(0.0)	1	(0.1)
Anxiety	8	(1.6)	3	(1.1)	11	(1.4)
Attention Deficit/Hyperactivity Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Depressed Mood	0	(0.0)	1	(0.4)	1	(0.1)
Depression	10	(2.0)	7	(2.5)	17	(2.2)
Initial Insomnia	0	(0.0)	1	(0.4)	1	(0.1)
Insomnia	17	(3.4)	10	(3.5)	27	(3.4)
Libido Decreased	1	(0.2)	1	(0.4)	2	(0.3)
Mental Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Mental Status Changes	1	(0.2)	1	(0.4)	2	(0.3)
Middle Insomnia	1	(0.2)	0	(0.0)	1	(0.1)
Obsessive Thoughts	1	(0.2)	0	(0.0)	1	(0.1)
Panic Attack	1	(0.2)	0	(0.0)	1	(0.1)
Restlessness	0	(0.0)	1	(0.4)	1	(0.1)
Sleep Disorder	3	(0.6)	4	(1.4)	7	(0.9)
Stress	3	(0.6)	0	(0.0)	3	(0.4)
Renal And Urinary Disorders	17	(3.4)	10	(3.5)	27	(3.4)
Bladder Pain	0	(0.0)	1	(0.4)	1	(0.1)
Costovertebral Angle Tenderness	1	(0.2)	0	(0.0)	1	(0.1)
Dysuria	1	(0.2)	4	(1.4)	5	(0.6)
Focal Glomerulosclerosis	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Renal And Urinary Disorders	17	(3.4)	10	(3.5)	27	(3.4)
Haematuria	0	(0.0)	1	(0.4)	1	(0.1)
Hypertonic Bladder	1	(0.2)	0	(0.0)	1	(0.1)
Nephrolithiasis	0	(0.0)	2	(0.7)	2	(0.3)
Nephropathy	0	(0.0)	1	(0.4)	1	(0.1)
Nephropathy Toxic	1	(0.2)	0	(0.0)	1	(0.1)
Nephrotic Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Nocturia	3	(0.6)	1	(0.4)	4	(0.5)
Pollakiuria	2	(0.4)	1	(0.4)	3	(0.4)
Polyuria	1	(0.2)	0	(0.0)	1	(0.1)
Renal Cyst	0	(0.0)	2	(0.7)	2	(0.3)
Renal Failure	2	(0.4)	0	(0.0)	2	(0.3)
Renal Failure Acute	0	(0.0)	1	(0.4)	1	(0.1)
Renal Impairment	1	(0.2)	0	(0.0)	1	(0.1)
Renal Pain	1	(0.2)	0	(0.0)	1	(0.1)
Renal Tubular Necrosis	1	(0.2)	0	(0.0)	1	(0.1)
Urinary Hesitation	1	(0.2)	0	(0.0)	1	(0.1)
Urinary Retention	1	(0.2)	1	(0.4)	2	(0.3)
Urinary Tract Obstruction	1	(0.2)	0	(0.0)	1	(0.1)
Reproductive System And Breast Disorders	17	(3.4)	5	(1.8)	22	(2.8)
Benign Prostatic Hyperplasia	1	(0.2)	0	(0.0)	1	(0.1)
Cervical Dysplasia	1	(0.2)	1	(0.4)	2	(0.3)
Ejaculation Disorder	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Reproductive System And Breast Disorders	17	(3.4)	5	(1.8)	22	(2.8)
Epididymitis	1	(0.2)	0	(0.0)	1	(0.1)
Erectile Dysfunction	4	(0.8)	1	(0.4)	5	(0.6)
Genital Pruritus Female	1	(0.2)	0	(0.0)	1	(0.1)
Gynaecomastia	1	(0.2)	0	(0.0)	1	(0.1)
Menstruation Irregular	0	(0.0)	1	(0.4)	1	(0.1)
Ovarian Cyst	1	(0.2)	0	(0.0)	1	(0.1)
Prostatitis	5	(1.0)	0	(0.0)	5	(0.6)
Scrotal Pain	0	(0.0)	1	(0.4)	1	(0.1)
Testicular Swelling	1	(0.2)	0	(0.0)	1	(0.1)
Vaginal Discharge	1	(0.2)	0	(0.0)	1	(0.1)
Respiratory, Thoracic And Mediastinal Disorders	56	(11.0)	34	(12.1)	90	(11.4)
Allergic Sinusitis	1	(0.2)	0	(0.0)	1	(0.1)
Asthma	5	(1.0)	2	(0.7)	7	(0.9)
Bronchopneumopathy	1	(0.2)	0	(0.0)	1	(0.1)
Bronchospasm	1	(0.2)	1	(0.4)	2	(0.3)
Cough	21	(4.1)	9	(3.2)	30	(3.8)
Dysphonia	2	(0.4)	0	(0.0)	2	(0.3)
Dyspnoea	2	(0.4)	3	(1.1)	5	(0.6)
Dyspnoea Exertional	1	(0.2)	2	(0.7)	3	(0.4)
Epistaxis	3	(0.6)	0	(0.0)	3	(0.4)
Hypoxia	0	(0.0)	1	(0.4)	1	(0.1)
Increased Upper Airway Secretion	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Respiratory, Thoracic And Mediastinal Disorders	56	(11.0)	34	(12.1)	90	(11.4)
Interstitial Lung Disease	1	(0.2)	1	(0.4)	2	(0.3)
Nasal Congestion	7	(1.4)	1	(0.4)	8	(1.0)
Paranasal Sinus Hypersecretion	2	(0.4)	1	(0.4)	3	(0.4)
Pharyngeal Erythema	1	(0.2)	1	(0.4)	2	(0.3)
Pharyngeal Ulceration	1	(0.2)	0	(0.0)	1	(0.1)
Pharyngolaryngeal Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Pharyngolaryngeal Pain	8	(1.6)	10	(3.5)	18	(2.3)
Pleural Effusion	1	(0.2)	0	(0.0)	1	(0.1)
Postnasal Drip	0	(0.0)	1	(0.4)	1	(0.1)
Productive Cough	3	(0.6)	1	(0.4)	4	(0.5)
Pulmonary Hypertension	0	(0.0)	1	(0.4)	1	(0.1)
Respiratory Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Rhinitis Allergic	0	(0.0)	2	(0.7)	2	(0.3)
Rhinitis Seasonal	0	(0.0)	1	(0.4)	1	(0.1)
Rhinorrhoea	2	(0.4)	2	(0.7)	4	(0.5)
Sinus Congestion	3	(0.6)	5	(1.8)	8	(1.0)
Sinus Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Sleep Apnoea Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Sneezing	0	(0.0)	1	(0.4)	1	(0.1)
Wheezing	3	(0.6)	0	(0.0)	3	(0.4)
Skin And Subcutaneous Tissue Disorders	112	(22.1)	57	(20.2)	169	(21.4)
Acne	4	(0.8)	0	(0.0)	4	(0.5)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	112	(22.1)	57	(20.2)	169	(21.4)
Acrodermatitis	1	(0.2)	0	(0.0)	1	(0.1)
Actinic Keratosis	0	(0.0)	1	(0.4)	1	(0.1)
Alopecia	2	(0.4)	1	(0.4)	3	(0.4)
Alopecia Effluvium	0	(0.0)	1	(0.4)	1	(0.1)
Blister	1	(0.2)	2	(0.7)	3	(0.4)
Dermal Cyst	1	(0.2)	3	(1.1)	4	(0.5)
Dermatitis	3	(0.6)	0	(0.0)	3	(0.4)
Dermatitis Acneiform	1	(0.2)	0	(0.0)	1	(0.1)
Dermatitis Allergic	1	(0.2)	0	(0.0)	1	(0.1)
Dermatitis Atopic	1	(0.2)	0	(0.0)	1	(0.1)
Dermatitis Contact	2	(0.4)	0	(0.0)	2	(0.3)
Dry Skin	3	(0.6)	3	(1.1)	6	(0.8)
Dyshidrosis	1	(0.2)	0	(0.0)	1	(0.1)
Eczema	2	(0.4)	6	(2.1)	8	(1.0)
Erythema	5	(1.0)	1	(0.4)	6	(0.8)
Erythema Nodosum	0	(0.0)	1	(0.4)	1	(0.1)
Fat Atrophy	1	(0.2)	0	(0.0)	1	(0.1)
Hyperhidrosis	8	(1.6)	2	(0.7)	10	(1.3)
Hyperkeratosis	0	(0.0)	1	(0.4)	1	(0.1)
Hypoaesthesia Facial	1	(0.2)	0	(0.0)	1	(0.1)
Lipoatrophy	1	(0.2)	1	(0.4)	2	(0.3)
Lipodystrophy Acquired	4	(0.8)	1	(0.4)	5	(0.6)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	112	(22.1)	57	(20.2)	169	(21.4)
Lipohypertrophy	3	(0.6)	1	(0.4)	4	(0.5)
Nail Discolouration	1	(0.2)	0	(0.0)	1	(0.1)
Neurodermatitis	1	(0.2)	0	(0.0)	1	(0.1)
Night Sweats	12	(2.4)	7	(2.5)	19	(2.4)
Palmar Erythema	0	(0.0)	1	(0.4)	1	(0.1)
Penile Ulceration	1	(0.2)	0	(0.0)	1	(0.1)
Photosensitivity Reaction	1	(0.2)	0	(0.0)	1	(0.1)
Pigmentation Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Pityriasis	1	(0.2)	0	(0.0)	1	(0.1)
Pityriasis Rosea	1	(0.2)	0	(0.0)	1	(0.1)
Prurigo	1	(0.2)	1	(0.4)	2	(0.3)
Pruritus	13	(2.6)	6	(2.1)	19	(2.4)
Pruritus Generalised	3	(0.6)	0	(0.0)	3	(0.4)
Psoriasis	1	(0.2)	0	(0.0)	1	(0.1)
Rash	23	(4.5)	8	(2.8)	31	(3.9)
Rash Follicular	1	(0.2)	0	(0.0)	1	(0.1)
Rash Generalised	1	(0.2)	0	(0.0)	1	(0.1)
Rash Macular	2	(0.4)	1	(0.4)	3	(0.4)
Rash Maculo-Papular	2	(0.4)	1	(0.4)	3	(0.4)
Rash Papular	4	(0.8)	1	(0.4)	5	(0.6)
Rash Pruritic	2	(0.4)	0	(0.0)	2	(0.3)
Rosacea	2	(0.4)	0	(0.0)	2	(0.3)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	112	(22.1)	57	(20.2)	169	(21.4)
Seborrhoeic Dermatitis	5	(1.0)	3	(1.1)	8	(1.0)
Skin Hyperpigmentation	0	(0.0)	1	(0.4)	1	(0.1)
Skin Irritation	0	(0.0)	1	(0.4)	1	(0.1)
Skin Lesion	4	(0.8)	3	(1.1)	7	(0.9)
Skin Nodule	2	(0.4)	3	(1.1)	5	(0.6)
Skin Ulcer	0	(0.0)	1	(0.4)	1	(0.1)
Stasis Dermatitis	1	(0.2)	0	(0.0)	1	(0.1)
Subcutaneous Nodule	4	(0.8)	4	(1.4)	8	(1.0)
Swelling Face	0	(0.0)	1	(0.4)	1	(0.1)
Urticaria	1	(0.2)	0	(0.0)	1	(0.1)
Xeroderma	2	(0.4)	0	(0.0)	2	(0.3)
Vascular Disorders	23	(4.5)	9	(3.2)	32	(4.1)
Deep Vein Thrombosis	1	(0.2)	0	(0.0)	1	(0.1)
Flushing	1	(0.2)	0	(0.0)	1	(0.1)
Haematoma	2	(0.4)	3	(1.1)	5	(0.6)
Hot Flush	2	(0.4)	0	(0.0)	2	(0.3)
Hyperaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hypertension	12	(2.4)	4	(1.4)	16	(2.0)
Hypotension	1	(0.2)	1	(0.4)	2	(0.3)
Shock	1	(0.2)	0	(0.0)	1	(0.1)
Thrombophlebitis	1	(0.2)	0	(0.0)	1	(0.1)
Varicophlebitis	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Vascular Disorders	23	(4.5)	9	(3.2)	32	(4.1)
Venous Thrombosis	1	(0.2)	0	(0.0)	1	(0.1)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005, P018, P019]

Appendix 2.7.4: 19

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	130	(25.6)	68	(24.1)	198	(25.1)
Patients With No Adverse Experience	377	(74.4)	214	(75.9)	591	(74.9)
Blood And Lymphatic System Disorders	3	(0.6)	5	(1.8)	8	(1.0)
Anaemia	1	(0.2)	3	(1.1)	4	(0.5)
Anaemia Macrocytic	1	(0.2)	0	(0.0)	1	(0.1)
Neutropenia	1	(0.2)	2	(0.7)	3	(0.4)
Cardiac Disorders	3	(0.6)	2	(0.7)	5	(0.6)
Arrhythmia	0	(0.0)	1	(0.4)	1	(0.1)
Cardiovascular Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Myocardial Infarction	1	(0.2)	0	(0.0)	1	(0.1)
Palpitations	1	(0.2)	0	(0.0)	1	(0.1)
Ventricular Extrasystoles	1	(0.2)	0	(0.0)	1	(0.1)
Ear And Labyrinth Disorders	2	(0.4)	0	(0.0)	2	(0.3)
Vertigo	2	(0.4)	0	(0.0)	2	(0.3)
Eye Disorders	1	(0.2)	0	(0.0)	1	(0.1)
Visual Disturbance	1	(0.2)	0	(0.0)	1	(0.1)
Gastrointestinal Disorders	38	(7.5)	29	(10.3)	67	(8.5)
Abdominal Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Distension	3	(0.6)	1	(0.4)	4	(0.5)
Abdominal Pain	6	(1.2)	2	(0.7)	8	(1.0)
Abdominal Pain Upper	1	(0.2)	1	(0.4)	2	(0.3)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	38	(7.5)	29	(10.3)	67	(8.5)
Constipation	2	(0.4)	0	(0.0)	2	(0.3)
Defaecation Urgency	0	(0.0)	1	(0.4)	1	(0.1)
Diarrhoea	19	(3.7)	13	(4.6)	32	(4.1)
Dry Mouth	0	(0.0)	1	(0.4)	1	(0.1)
Dyspepsia	1	(0.2)	2	(0.7)	3	(0.4)
Flatulence	1	(0.2)	0	(0.0)	1	(0.1)
Gastritis	1	(0.2)	1	(0.4)	2	(0.3)
Gastrointestinal Pain	2	(0.4)	0	(0.0)	2	(0.3)
Gastrooesophageal Reflux Disease	1	(0.2)	1	(0.4)	2	(0.3)
Glossitis	1	(0.2)	0	(0.0)	1	(0.1)
Mouth Ulceration	0	(0.0)	1	(0.4)	1	(0.1)
Nausea	11	(2.2)	9	(3.2)	20	(2.5)
Pancreatitis	0	(0.0)	1	(0.4)	1	(0.1)
Stomach Discomfort	0	(0.0)	1	(0.4)	1	(0.1)
Vomiting	5	(1.0)	5	(1.8)	10	(1.3)
General Disorders And Administration Site Conditions	44	(8.7)	13	(4.6)	57	(7.2)
Asthenia	7	(1.4)	1	(0.4)	8	(1.0)
Chest Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Chills	1	(0.2)	0	(0.0)	1	(0.1)
Drug Intolerance	0	(0.0)	1	(0.4)	1	(0.1)
Fatigue	5	(1.0)	2	(0.7)	7	(0.9)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	44	(8.7)	13	(4.6)	57	(7.2)
Feeling Hot	1	(0.2)	0	(0.0)	1	(0.1)
Inflammation	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Erythema	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Induration	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Inflammation	0	(0.0)	1	(0.4)	1	(0.1)
Injection Site Irritation	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Pain	6	(1.2)	1	(0.4)	7	(0.9)
Injection Site Reaction	14	(2.8)	8	(2.8)	22	(2.8)
Injection Site Swelling	4	(0.8)	0	(0.0)	4	(0.5)
Irritability	1	(0.2)	0	(0.0)	1	(0.1)
Nodule	1	(0.2)	0	(0.0)	1	(0.1)
Pyrexia	4	(0.8)	0	(0.0)	4	(0.5)
Hepatobiliary Disorders	4	(0.8)	3	(1.1)	7	(0.9)
Cholestasis	0	(0.0)	1	(0.4)	1	(0.1)
Hepatitis	2	(0.4)	0	(0.0)	2	(0.3)
Hepatitis Toxic	0	(0.0)	1	(0.4)	1	(0.1)
Hepatomegaly	1	(0.2)	1	(0.4)	2	(0.3)
Hyperbilirubinaemia	1	(0.2)	0	(0.0)	1	(0.1)
Immune System Disorders	3	(0.6)	3	(1.1)	6	(0.8)
Drug Hypersensitivity	2	(0.4)	1	(0.4)	3	(0.4)
Hypersensitivity	2	(0.4)	1	(0.4)	3	(0.4)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Immune System Disorders	3	(0.6)	3	(1.1)	6	(0.8)
Immune Reconstitution Syndrome	0	(0.0)	1	(0.4)	1	(0.1)
Infections And Infestations	4	(0.8)	0	(0.0)	4	(0.5)
Cellulitis	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Simplex	2	(0.4)	0	(0.0)	2	(0.3)
Skin Infection	1	(0.2)	0	(0.0)	1	(0.1)
Investigations	2	(0.4)	2	(0.7)	4	(0.5)
Weight Decreased	1	(0.2)	2	(0.7)	3	(0.4)
Weight Increased	1	(0.2)	0	(0.0)	1	(0.1)
Metabolism And Nutrition Disorders	10	(2.0)	3	(1.1)	13	(1.6)
Central Obesity	1	(0.2)	0	(0.0)	1	(0.1)
Diabetes Mellitus	2	(0.4)	0	(0.0)	2	(0.3)
Dyslipidaemia	2	(0.4)	0	(0.0)	2	(0.3)
Facial Wasting	1	(0.2)	0	(0.0)	1	(0.1)
Hypercholesterolaemia	0	(0.0)	1	(0.4)	1	(0.1)
Hyperglycaemia	0	(0.0)	1	(0.4)	1	(0.1)
Hyperlactacidaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hyperlipidaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hypertriglyceridaemia	1	(0.2)	1	(0.4)	2	(0.3)
Increased Appetite	1	(0.2)	0	(0.0)	1	(0.1)
Lipomatosis	1	(0.2)	0	(0.0)	1	(0.1)
Musculoskeletal And Connective Tissue Disorders	10	(2.0)	2	(0.7)	12	(1.5)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	10	(2.0)	2	(0.7)	12	(1.5)
Arthralgia	4	(0.8)	0	(0.0)	4	(0.5)
Back Pain	1	(0.2)	0	(0.0)	1	(0.1)
Muscle Atrophy	1	(0.2)	0	(0.0)	1	(0.1)
Muscle Spasms	1	(0.2)	0	(0.0)	1	(0.1)
Musculoskeletal Pain	1	(0.2)	0	(0.0)	1	(0.1)
Myalgia	2	(0.4)	2	(0.7)	4	(0.5)
Myositis	1	(0.2)	0	(0.0)	1	(0.1)
Pain In Extremity	2	(0.4)	0	(0.0)	2	(0.3)
Nervous System Disorders	24	(4.7)	9	(3.2)	33	(4.2)
Allodynia	1	(0.2)	0	(0.0)	1	(0.1)
Dizziness	6	(1.2)	1	(0.4)	7	(0.9)
Dysgeusia	0	(0.0)	1	(0.4)	1	(0.1)
Headache	12	(2.4)	4	(1.4)	16	(2.0)
Migraine	0	(0.0)	1	(0.4)	1	(0.1)
Neuropathy	1	(0.2)	1	(0.4)	2	(0.3)
Neuropathy Peripheral	2	(0.4)	0	(0.0)	2	(0.3)
Paraesthesia	1	(0.2)	1	(0.4)	2	(0.3)
Polyneuropathy	1	(0.2)	0	(0.0)	1	(0.1)
Somnolence	1	(0.2)	1	(0.4)	2	(0.3)
Syncope	0	(0.0)	1	(0.4)	1	(0.1)
Tension Headache	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Psychiatric Disorders	6	(1.2)	3	(1.1)	9	(1.1)
Abnormal Dreams	1	(0.2)	0	(0.0)	1	(0.1)
Anxiety	1	(0.2)	0	(0.0)	1	(0.1)
Depression	2	(0.4)	1	(0.4)	3	(0.4)
Insomnia	2	(0.4)	0	(0.0)	2	(0.3)
Libido Decreased	0	(0.0)	1	(0.4)	1	(0.1)
Mental Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Renal And Urinary Disorders	6	(1.2)	4	(1.4)	10	(1.3)
Dysuria	0	(0.0)	1	(0.4)	1	(0.1)
Nephrolithiasis	0	(0.0)	1	(0.4)	1	(0.1)
Nephropathy Toxic	1	(0.2)	0	(0.0)	1	(0.1)
Nephrotic Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Nocturia	1	(0.2)	0	(0.0)	1	(0.1)
Pollakiuria	1	(0.2)	1	(0.4)	2	(0.3)
Renal Failure	1	(0.2)	1	(0.4)	2	(0.3)
Renal Failure Chronic	1	(0.2)	0	(0.0)	1	(0.1)
Renal Impairment	1	(0.2)	0	(0.0)	1	(0.1)
Renal Tubular Necrosis	1	(0.2)	0	(0.0)	1	(0.1)
Reproductive System And Breast Disorders	2	(0.4)	0	(0.0)	2	(0.3)
Erectile Dysfunction	1	(0.2)	0	(0.0)	1	(0.1)
Gynaecomastia	1	(0.2)	0	(0.0)	1	(0.1)
Respiratory, Thoracic And Mediastinal Disorders	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Respiratory, Thoracic And Mediastinal Disorders	1	(0.2)	0	(0.0)	1	(0.1)
Epistaxis	1	(0.2)	0	(0.0)	1	(0.1)
Skin And Subcutaneous Tissue Disorders	19	(3.7)	12	(4.3)	31	(3.9)
Dermatitis Acneiform	1	(0.2)	0	(0.0)	1	(0.1)
Erythema	2	(0.4)	0	(0.0)	2	(0.3)
Exfoliative Rash	0	(0.0)	1	(0.4)	1	(0.1)
Hyperhidrosis	2	(0.4)	0	(0.0)	2	(0.3)
Lipoatrophy	1	(0.2)	1	(0.4)	2	(0.3)
Lipodystrophy Acquired	6	(1.2)	2	(0.7)	8	(1.0)
Night Sweats	1	(0.2)	0	(0.0)	1	(0.1)
Prurigo	1	(0.2)	0	(0.0)	1	(0.1)
Pruritus	0	(0.0)	1	(0.4)	1	(0.1)
Rash	4	(0.8)	2	(0.7)	6	(0.8)
Rash Macular	1	(0.2)	1	(0.4)	2	(0.3)
Rash Maculo-Papular	1	(0.2)	1	(0.4)	2	(0.3)
Skin Nodule	0	(0.0)	2	(0.7)	2	(0.3)
Subcutaneous Nodule	2	(0.4)	1	(0.4)	3	(0.4)
Systemic Lupus Erythematosus Rash	0	(0.0)	1	(0.4)	1	(0.1)
Xeroderma	1	(0.2)	0	(0.0)	1	(0.1)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.
Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).
Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005-Define, P018-Define, P019-Define]

Appendix 2.7.4: 20

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Patients With One Or More Drug-Related Adverse Experiences	119	(23.5)	60	(21.3)	179	(22.7)
Patients With No Drug-Related Adverse Experience	388	(76.5)	222	(78.7)	610	(77.3)
Blood And Lymphatic System Disorders	3	(0.6)	5	(1.8)	8	(1.0)
Anaemia	1	(0.2)	3	(1.1)	4	(0.5)
Anaemia Macrocytic	1	(0.2)	0	(0.0)	1	(0.1)
Neutropenia	1	(0.2)	2	(0.7)	3	(0.4)
Cardiac Disorders	3	(0.6)	2	(0.7)	5	(0.6)
Arrhythmia	0	(0.0)	1	(0.4)	1	(0.1)
Cardiovascular Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Myocardial Infarction	1	(0.2)	0	(0.0)	1	(0.1)
Palpitations	1	(0.2)	0	(0.0)	1	(0.1)
Ventricular Extrasystoles	1	(0.2)	0	(0.0)	1	(0.1)
Ear And Labyrinth Disorders	2	(0.4)	0	(0.0)	2	(0.3)
Vertigo	2	(0.4)	0	(0.0)	2	(0.3)
Eye Disorders	1	(0.2)	0	(0.0)	1	(0.1)
Visual Disturbance	1	(0.2)	0	(0.0)	1	(0.1)
Gastrointestinal Disorders	38	(7.5)	26	(9.2)	64	(8.1)
Abdominal Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Distension	3	(0.6)	1	(0.4)	4	(0.5)
Abdominal Pain	6	(1.2)	2	(0.7)	8	(1.0)
Abdominal Pain Upper	2	(0.4)	1	(0.4)	3	(0.4)
Constipation	2	(0.4)	0	(0.0)	2	(0.3)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	38	(7.5)	26	(9.2)	64	(8.1)
Defaecation Urgency	0	(0.0)	1	(0.4)	1	(0.1)
Diarrhoea	19	(3.7)	10	(3.5)	29	(3.7)
Dry Mouth	0	(0.0)	1	(0.4)	1	(0.1)
Dyspepsia	1	(0.2)	2	(0.7)	3	(0.4)
Flatulence	1	(0.2)	0	(0.0)	1	(0.1)
Gastritis	1	(0.2)	1	(0.4)	2	(0.3)
Gastrointestinal Pain	2	(0.4)	0	(0.0)	2	(0.3)
Gastrooesophageal Reflux Disease	0	(0.0)	1	(0.4)	1	(0.1)
Glossitis	1	(0.2)	0	(0.0)	1	(0.1)
Mouth Ulceration	0	(0.0)	1	(0.4)	1	(0.1)
Nausea	11	(2.2)	9	(3.2)	20	(2.5)
Pancreatitis	0	(0.0)	1	(0.4)	1	(0.1)
Stomach Discomfort	0	(0.0)	1	(0.4)	1	(0.1)
Vomiting	4	(0.8)	5	(1.8)	9	(1.1)
General Disorders And Administration Site Conditions	42	(8.3)	13	(4.6)	55	(7.0)
Asthenia	7	(1.4)	1	(0.4)	8	(1.0)
Chest Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Chills	1	(0.2)	0	(0.0)	1	(0.1)
Drug Intolerance	0	(0.0)	1	(0.4)	1	(0.1)
Fatigue	5	(1.0)	2	(0.7)	7	(0.9)
Feeling Hot	1	(0.2)	0	(0.0)	1	(0.1)
Inflammation	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	42	(8.3)	13	(4.6)	55	(7.0)
Injection Site Erythema	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Induration	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Inflammation	0	(0.0)	1	(0.4)	1	(0.1)
Injection Site Irritation	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Pain	5	(1.0)	1	(0.4)	6	(0.8)
Injection Site Reaction	12	(2.4)	8	(2.8)	20	(2.5)
Injection Site Swelling	4	(0.8)	0	(0.0)	4	(0.5)
Irritability	1	(0.2)	0	(0.0)	1	(0.1)
Nodule	1	(0.2)	0	(0.0)	1	(0.1)
Pyrexia	4	(0.8)	0	(0.0)	4	(0.5)
Hepatobiliary Disorders	3	(0.6)	2	(0.7)	5	(0.6)
Cholestasis	0	(0.0)	1	(0.4)	1	(0.1)
Hepatitis	2	(0.4)	0	(0.0)	2	(0.3)
Hepatomegaly	1	(0.2)	1	(0.4)	2	(0.3)
Immune System Disorders	3	(0.6)	1	(0.4)	4	(0.5)
Drug Hypersensitivity	2	(0.4)	0	(0.0)	2	(0.3)
Hypersensitivity	2	(0.4)	1	(0.4)	3	(0.4)
Infections And Infestations	3	(0.6)	0	(0.0)	3	(0.4)
Cellulitis	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Simplex	1	(0.2)	0	(0.0)	1	(0.1)
Skin Infection	1	(0.2)	0	(0.0)	1	(0.1)
Investigations	1	(0.2)	2	(0.7)	3	(0.4)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Investigations	1	(0.2)	2	(0.7)	3	(0.4)
Weight Decreased	1	(0.2)	2	(0.7)	3	(0.4)
Metabolism And Nutrition Disorders	9	(1.8)	3	(1.1)	12	(1.5)
Body Fat Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Central Obesity	1	(0.2)	0	(0.0)	1	(0.1)
Diabetes Mellitus	2	(0.4)	0	(0.0)	2	(0.3)
Dyslipidaemia	1	(0.2)	0	(0.0)	1	(0.1)
Facial Wasting	1	(0.2)	0	(0.0)	1	(0.1)
Hypercholesterolaemia	0	(0.0)	1	(0.4)	1	(0.1)
Hyperglycaemia	0	(0.0)	1	(0.4)	1	(0.1)
Hyperlactacidaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hyperlipidaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hypertriglyceridaemia	1	(0.2)	1	(0.4)	2	(0.3)
Increased Appetite	1	(0.2)	0	(0.0)	1	(0.1)
Musculoskeletal And Connective Tissue Disorders	8	(1.6)	2	(0.7)	10	(1.3)
Arthralgia	3	(0.6)	0	(0.0)	3	(0.4)
Back Pain	1	(0.2)	0	(0.0)	1	(0.1)
Muscle Spasms	1	(0.2)	0	(0.0)	1	(0.1)
Musculoskeletal Pain	1	(0.2)	0	(0.0)	1	(0.1)
Myalgia	1	(0.2)	2	(0.7)	3	(0.4)
Myositis	1	(0.2)	0	(0.0)	1	(0.1)
Pain In Extremity	2	(0.4)	0	(0.0)	2	(0.3)
Nervous System Disorders	23	(4.5)	9	(3.2)	32	(4.1)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Nervous System Disorders	23	(4.5)	9	(3.2)	32	(4.1)
Allodynia	1	(0.2)	0	(0.0)	1	(0.1)
Dizziness	6	(1.2)	1	(0.4)	7	(0.9)
Dysgeusia	0	(0.0)	1	(0.4)	1	(0.1)
Headache	11	(2.2)	4	(1.4)	15	(1.9)
Migraine	0	(0.0)	1	(0.4)	1	(0.1)
Neuropathy	1	(0.2)	1	(0.4)	2	(0.3)
Neuropathy Peripheral	2	(0.4)	0	(0.0)	2	(0.3)
Paraesthesia	1	(0.2)	1	(0.4)	2	(0.3)
Polyneuropathy	1	(0.2)	0	(0.0)	1	(0.1)
Somnolence	1	(0.2)	1	(0.4)	2	(0.3)
Syncope	0	(0.0)	1	(0.4)	1	(0.1)
Tension Headache	1	(0.2)	0	(0.0)	1	(0.1)
Psychiatric Disorders	6	(1.2)	3	(1.1)	9	(1.1)
Abnormal Dreams	1	(0.2)	0	(0.0)	1	(0.1)
Anxiety	1	(0.2)	0	(0.0)	1	(0.1)
Depression	2	(0.4)	1	(0.4)	3	(0.4)
Insomnia	2	(0.4)	0	(0.0)	2	(0.3)
Libido Decreased	0	(0.0)	1	(0.4)	1	(0.1)
Mental Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Renal And Urinary Disorders	5	(1.0)	2	(0.7)	7	(0.9)
Nephrolithiasis	0	(0.0)	1	(0.4)	1	(0.1)
Nephropathy Toxic	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Renal And Urinary Disorders	5	(1.0)	2	(0.7)	7	(0.9)
Nephrotic Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Nocturia	1	(0.2)	0	(0.0)	1	(0.1)
Pollakiuria	1	(0.2)	1	(0.4)	2	(0.3)
Renal Failure	1	(0.2)	0	(0.0)	1	(0.1)
Renal Impairment	1	(0.2)	0	(0.0)	1	(0.1)
Reproductive System And Breast Disorders	2	(0.4)	0	(0.0)	2	(0.3)
Erectile Dysfunction	1	(0.2)	0	(0.0)	1	(0.1)
Gynaecomastia	1	(0.2)	0	(0.0)	1	(0.1)
Respiratory, Thoracic And Mediastinal Disorders	1	(0.2)	0	(0.0)	1	(0.1)
Epistaxis	1	(0.2)	0	(0.0)	1	(0.1)
Skin And Subcutaneous Tissue Disorders	15	(3.0)	11	(3.9)	26	(3.3)
Dermatitis Acneiform	1	(0.2)	0	(0.0)	1	(0.1)
Erythema	1	(0.2)	0	(0.0)	1	(0.1)
Fat Atrophy	1	(0.2)	0	(0.0)	1	(0.1)
Hyperhidrosis	2	(0.4)	0	(0.0)	2	(0.3)
Lipoatrophy	1	(0.2)	1	(0.4)	2	(0.3)
Lipodystrophy Acquired	4	(0.8)	1	(0.4)	5	(0.6)
Night Sweats	1	(0.2)	0	(0.0)	1	(0.1)
Prurigo	0	(0.0)	1	(0.4)	1	(0.1)
Pruritus	0	(0.0)	1	(0.4)	1	(0.1)
Rash	4	(0.8)	2	(0.7)	6	(0.8)
Rash Macular	1	(0.2)	1	(0.4)	2	(0.3)

Number (%) of Patients With Specific Drug-Related Clinical Adverse Experiences of Moderate or Severe Intensity (Incidence >0% in One or More Treatment Groups) by System Organ Class (Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort) (Protocols 005, 018, 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	15	(3.0)	11	(3.9)	26	(3.3)
Rash Maculo-Papular	1	(0.2)	1	(0.4)	2	(0.3)
Skin Nodule	0	(0.0)	2	(0.7)	2	(0.3)
Subcutaneous Nodule	1	(0.2)	1	(0.4)	2	(0.3)
Xeroderma	1	(0.2)	0	(0.0)	1	(0.1)

Although a patient may have had two or more clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.
Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).
Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005, P018, P019]

Appendix 2.7.4: 21

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Patients With One Or More Adverse Experiences	257	(50.7)	152	(53.9)	409	(51.8)
Patients With No Adverse Experience	250	(49.3)	130	(46.1)	380	(48.2)
Blood And Lymphatic System Disorders	5	(1.0)	8	(2.8)	13	(1.6)
Anaemia	2	(0.4)	4	(1.4)	6	(0.8)
Anaemia Macrocytic	1	(0.2)	0	(0.0)	1	(0.1)
Iron Deficiency Anaemia	1	(0.2)	0	(0.0)	1	(0.1)
Lymphadenopathy	0	(0.0)	2	(0.7)	2	(0.3)
Neutropenia	2	(0.4)	2	(0.7)	4	(0.5)
Cardiac Disorders	4	(0.8)	2	(0.7)	6	(0.8)
Arrhythmia	0	(0.0)	1	(0.4)	1	(0.1)
Cardiovascular Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Myocardial Infarction	1	(0.2)	0	(0.0)	1	(0.1)
Palpitations	2	(0.4)	0	(0.0)	2	(0.3)
Ventricular Extrasystoles	1	(0.2)	0	(0.0)	1	(0.1)
Congenital, Familial And Genetic Disorders	0	(0.0)	1	(0.4)	1	(0.1)
Fanconi Syndrome	0	(0.0)	1	(0.4)	1	(0.1)
Ear And Labyrinth Disorders	5	(1.0)	0	(0.0)	5	(0.6)
Vertigo	5	(1.0)	0	(0.0)	5	(0.6)
Eye Disorders	3	(0.6)	3	(1.1)	6	(0.8)
Conjunctival Hyperaemia	0	(0.0)	1	(0.4)	1	(0.1)
Eye Movement Disorder	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Eye Disorders	3	(0.6)	3	(1.1)	6	(0.8)
Lacrimation Increased	0	(0.0)	1	(0.4)	1	(0.1)
Ocular Icterus	1	(0.2)	0	(0.0)	1	(0.1)
Visual Acuity Reduced	1	(0.2)	0	(0.0)	1	(0.1)
Visual Disturbance	1	(0.2)	0	(0.0)	1	(0.1)
Gastrointestinal Disorders	109	(21.5)	70	(24.8)	179	(22.7)
Abdominal Discomfort	3	(0.6)	0	(0.0)	3	(0.4)
Abdominal Distension	10	(2.0)	6	(2.1)	16	(2.0)
Abdominal Mass	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Pain	14	(2.8)	6	(2.1)	20	(2.5)
Abdominal Pain Upper	4	(0.8)	2	(0.7)	6	(0.8)
Anal Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Bowel Sounds Abnormal	0	(0.0)	1	(0.4)	1	(0.1)
Chapped Lips	1	(0.2)	0	(0.0)	1	(0.1)
Constipation	6	(1.2)	1	(0.4)	7	(0.9)
Defaecation Urgency	0	(0.0)	2	(0.7)	2	(0.3)
Diarrhoea	46	(9.1)	36	(12.8)	82	(10.4)
Dry Mouth	2	(0.4)	1	(0.4)	3	(0.4)
Dyspepsia	2	(0.4)	4	(1.4)	6	(0.8)
Eructation	1	(0.2)	1	(0.4)	2	(0.3)
Flatulence	11	(2.2)	5	(1.8)	16	(2.0)
Gastric Disorder	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	109	(21.5)	70	(24.8)	179	(22.7)
Gastritis	2	(0.4)	2	(0.7)	4	(0.5)
Gastrointestinal Pain	2	(0.4)	0	(0.0)	2	(0.3)
Gastrooesophageal Reflux Disease	4	(0.8)	1	(0.4)	5	(0.6)
Glossitis	1	(0.2)	0	(0.0)	1	(0.1)
Hypoaesthesia Oral	0	(0.0)	1	(0.4)	1	(0.1)
Mouth Ulceration	0	(0.0)	1	(0.4)	1	(0.1)
Nausea	32	(6.3)	23	(8.2)	55	(7.0)
Odynophagia	1	(0.2)	0	(0.0)	1	(0.1)
Oral Pain	1	(0.2)	0	(0.0)	1	(0.1)
Pancreatitis	0	(0.0)	1	(0.4)	1	(0.1)
Pancreatitis Acute	1	(0.2)	0	(0.0)	1	(0.1)
Peptic Ulcer	1	(0.2)	0	(0.0)	1	(0.1)
Rectal Haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)
Salivary Hypersecretion	0	(0.0)	1	(0.4)	1	(0.1)
Stomach Discomfort	1	(0.2)	1	(0.4)	2	(0.3)
Vomiting	14	(2.8)	13	(4.6)	27	(3.4)
General Disorders And Administration Site Conditions	102	(20.1)	50	(17.7)	152	(19.3)
Asthenia	8	(1.6)	2	(0.7)	10	(1.3)
Chest Discomfort	2	(0.4)	1	(0.4)	3	(0.4)
Chills	1	(0.2)	0	(0.0)	1	(0.1)
Drug Intolerance	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	102	(20.1)	50	(17.7)	152	(19.3)
Fatigue	15	(3.0)	4	(1.4)	19	(2.4)
Feeling Abnormal	0	(0.0)	2	(0.7)	2	(0.3)
Feeling Hot	1	(0.2)	0	(0.0)	1	(0.1)
Feeling Jittery	1	(0.2)	0	(0.0)	1	(0.1)
Induration	0	(0.0)	1	(0.4)	1	(0.1)
Inflammation	1	(0.2)	0	(0.0)	1	(0.1)
Influenza Like Illness	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Bruising	3	(0.6)	0	(0.0)	3	(0.4)
Injection Site Erythema	4	(0.8)	1	(0.4)	5	(0.6)
Injection Site Haemorrhage	2	(0.4)	0	(0.0)	2	(0.3)
Injection Site Induration	4	(0.8)	0	(0.0)	4	(0.5)
Injection Site Inflammation	1	(0.2)	1	(0.4)	2	(0.3)
Injection Site Irritation	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Nodule	5	(1.0)	5	(1.8)	10	(1.3)
Injection Site Pain	8	(1.6)	2	(0.7)	10	(1.3)
Injection Site Pruritus	1	(0.2)	1	(0.4)	2	(0.3)
Injection Site Reaction	50	(9.9)	28	(9.9)	78	(9.9)
Injection Site Swelling	4	(0.8)	0	(0.0)	4	(0.5)
Irritability	1	(0.2)	0	(0.0)	1	(0.1)
Malaise	0	(0.0)	1	(0.4)	1	(0.1)
Nodule	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	102	(20.1)	50	(17.7)	152	(19.3)
Oedema Peripheral	1	(0.2)	0	(0.0)	1	(0.1)
Pyrexia	5	(1.0)	6	(2.1)	11	(1.4)
Xerosis	1	(0.2)	0	(0.0)	1	(0.1)
Hepatobiliary Disorders	8	(1.6)	4	(1.4)	12	(1.5)
Cholestasis	0	(0.0)	1	(0.4)	1	(0.1)
Hepatitis	2	(0.4)	1	(0.4)	3	(0.4)
Hepatitis Toxic	0	(0.0)	1	(0.4)	1	(0.1)
Hepatomegaly	1	(0.2)	1	(0.4)	2	(0.3)
Hyperbilirubinaemia	2	(0.4)	0	(0.0)	2	(0.3)
Jaundice	3	(0.6)	1	(0.4)	4	(0.5)
Immune System Disorders	3	(0.6)	3	(1.1)	6	(0.8)
Drug Hypersensitivity	2	(0.4)	1	(0.4)	3	(0.4)
Hypersensitivity	2	(0.4)	1	(0.4)	3	(0.4)
Immune Reconstitution Syndrome	0	(0.0)	1	(0.4)	1	(0.1)
Infections And Infestations	11	(2.2)	1	(0.4)	12	(1.5)
Cellulitis	1	(0.2)	0	(0.0)	1	(0.1)
Folliculitis	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Simplex	2	(0.4)	0	(0.0)	2	(0.3)
Herpes Virus Infection	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Zoster	2	(0.4)	0	(0.0)	2	(0.3)
Influenza	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Infections And Infestations	11	(2.2)	1	(0.4)	12	(1.5)
Molluscum Contagiosum	1	(0.2)	0	(0.0)	1	(0.1)
Nasopharyngitis	0	(0.0)	1	(0.4)	1	(0.1)
Paronychia	1	(0.2)	0	(0.0)	1	(0.1)
Skin Infection	1	(0.2)	0	(0.0)	1	(0.1)
Injury, Poisoning And Procedural Complications	1	(0.2)	0	(0.0)	1	(0.1)
Accidental Overdose	1	(0.2)	0	(0.0)	1	(0.1)
Investigations	4	(0.8)	3	(1.1)	7	(0.9)
Electrocardiogram PR Prolongation	1	(0.2)	0	(0.0)	1	(0.1)
Weight Decreased	1	(0.2)	2	(0.7)	3	(0.4)
Weight Increased	2	(0.4)	1	(0.4)	3	(0.4)
Metabolism And Nutrition Disorders	23	(4.5)	13	(4.6)	36	(4.6)
Anorexia	1	(0.2)	2	(0.7)	3	(0.4)
Central Obesity	1	(0.2)	0	(0.0)	1	(0.1)
Decreased Appetite	6	(1.2)	4	(1.4)	10	(1.3)
Dehydration	0	(0.0)	1	(0.4)	1	(0.1)
Diabetes Mellitus	3	(0.6)	0	(0.0)	3	(0.4)
Dyslipidaemia	2	(0.4)	0	(0.0)	2	(0.3)
Facial Wasting	1	(0.2)	0	(0.0)	1	(0.1)
Hypercholesterolaemia	2	(0.4)	2	(0.7)	4	(0.5)
Hyperglycaemia	1	(0.2)	1	(0.4)	2	(0.3)
Hyperlactacidaemia	3	(0.6)	0	(0.0)	3	(0.4)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	23	(4.5)	13	(4.6)	36	(4.6)
Hyperlipidaemia	2	(0.4)	0	(0.0)	2	(0.3)
Hypertriglyceridaemia	1	(0.2)	3	(1.1)	4	(0.5)
Increased Appetite	1	(0.2)	0	(0.0)	1	(0.1)
Lipomatosis	1	(0.2)	0	(0.0)	1	(0.1)
Musculoskeletal And Connective Tissue Disorders	16	(3.2)	4	(1.4)	20	(2.5)
Arthralgia	6	(1.2)	0	(0.0)	6	(0.8)
Back Pain	1	(0.2)	0	(0.0)	1	(0.1)
Muscle Atrophy	1	(0.2)	0	(0.0)	1	(0.1)
Muscle Hypertrophy	0	(0.0)	1	(0.4)	1	(0.1)
Muscle Spasms	1	(0.2)	1	(0.4)	2	(0.3)
Musculoskeletal Pain	1	(0.2)	0	(0.0)	1	(0.1)
Myalgia	4	(0.8)	2	(0.7)	6	(0.8)
Myositis	1	(0.2)	0	(0.0)	1	(0.1)
Pain In Extremity	4	(0.8)	0	(0.0)	4	(0.5)
Tendonitis	1	(0.2)	0	(0.0)	1	(0.1)
Nervous System Disorders	55	(10.8)	31	(11.0)	86	(10.9)
Ageusia	0	(0.0)	1	(0.4)	1	(0.1)
Allodynia	1	(0.2)	0	(0.0)	1	(0.1)
Carpal Tunnel Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Dizziness	7	(1.4)	3	(1.1)	10	(1.3)
Dizziness Postural	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Nervous System Disorders	55	(10.8)	31	(11.0)	86	(10.9)
Dysgeusia	5	(1.0)	3	(1.1)	8	(1.0)
Headache	27	(5.3)	16	(5.7)	43	(5.4)
Hypersomnia	1	(0.2)	0	(0.0)	1	(0.1)
Hypoaesthesia	2	(0.4)	1	(0.4)	3	(0.4)
Lacunar Infarction	0	(0.0)	1	(0.4)	1	(0.1)
Lethargy	1	(0.2)	0	(0.0)	1	(0.1)
Migraine	0	(0.0)	1	(0.4)	1	(0.1)
Neuropathy	3	(0.6)	2	(0.7)	5	(0.6)
Neuropathy Peripheral	3	(0.6)	1	(0.4)	4	(0.5)
Paraesthesia	1	(0.2)	2	(0.7)	3	(0.4)
Parosmia	0	(0.0)	1	(0.4)	1	(0.1)
Polyneuropathy	1	(0.2)	0	(0.0)	1	(0.1)
Somnolence	4	(0.8)	2	(0.7)	6	(0.8)
Syncope	1	(0.2)	1	(0.4)	2	(0.3)
Tension Headache	1	(0.2)	0	(0.0)	1	(0.1)
Transient Ischaemic Attack	0	(0.0)	1	(0.4)	1	(0.1)
Psychiatric Disorders	17	(3.4)	12	(4.3)	29	(3.7)
Abnormal Dreams	3	(0.6)	3	(1.1)	6	(0.8)
Anxiety	2	(0.4)	1	(0.4)	3	(0.4)
Depressed Mood	0	(0.0)	1	(0.4)	1	(0.1)
Depression	3	(0.6)	1	(0.4)	4	(0.5)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Psychiatric Disorders	17	(3.4)	12	(4.3)	29	(3.7)
Initial Insomnia	0	(0.0)	1	(0.4)	1	(0.1)
Insomnia	7	(1.4)	4	(1.4)	11	(1.4)
Libido Decreased	0	(0.0)	1	(0.4)	1	(0.1)
Mental Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Middle Insomnia	1	(0.2)	0	(0.0)	1	(0.1)
Restlessness	0	(0.0)	1	(0.4)	1	(0.1)
Sleep Disorder	2	(0.4)	0	(0.0)	2	(0.3)
Renal And Urinary Disorders	9	(1.8)	7	(2.5)	16	(2.0)
Dysuria	0	(0.0)	2	(0.7)	2	(0.3)
Glycosuria	1	(0.2)	0	(0.0)	1	(0.1)
Nephrolithiasis	0	(0.0)	1	(0.4)	1	(0.1)
Nephropathy	1	(0.2)	0	(0.0)	1	(0.1)
Nephropathy Toxic	1	(0.2)	0	(0.0)	1	(0.1)
Nephrotic Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Nocturia	2	(0.4)	1	(0.4)	3	(0.4)
Pollakiuria	1	(0.2)	1	(0.4)	2	(0.3)
Renal Failure	1	(0.2)	1	(0.4)	2	(0.3)
Renal Failure Chronic	1	(0.2)	0	(0.0)	1	(0.1)
Renal Impairment	1	(0.2)	0	(0.0)	1	(0.1)
Renal Tubular Necrosis	1	(0.2)	0	(0.0)	1	(0.1)
Urinary Retention	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Reproductive System And Breast Disorders	4	(0.8)	0	(0.0)	4	(0.5)
Erectile Dysfunction	1	(0.2)	0	(0.0)	1	(0.1)
Gynaecomastia	2	(0.4)	0	(0.0)	2	(0.3)
Menopausal Symptoms	1	(0.2)	0	(0.0)	1	(0.1)
Respiratory, Thoracic And Mediastinal Disorders	4	(0.8)	1	(0.4)	5	(0.6)
Cough	0	(0.0)	1	(0.4)	1	(0.1)
Dysphonia	1	(0.2)	0	(0.0)	1	(0.1)
Epistaxis	1	(0.2)	0	(0.0)	1	(0.1)
Nasal Congestion	1	(0.2)	0	(0.0)	1	(0.1)
Pharyngeal Erythema	1	(0.2)	0	(0.0)	1	(0.1)
Skin And Subcutaneous Tissue Disorders	43	(8.5)	27	(9.6)	70	(8.9)
Alopecia	0	(0.0)	1	(0.4)	1	(0.1)
Alopecia Effluvium	0	(0.0)	1	(0.4)	1	(0.1)
Dermatitis Acneiform	1	(0.2)	0	(0.0)	1	(0.1)
Dry Skin	1	(0.2)	0	(0.0)	1	(0.1)
Eczema	0	(0.0)	1	(0.4)	1	(0.1)
Erythema	2	(0.4)	0	(0.0)	2	(0.3)
Exfoliative Rash	0	(0.0)	1	(0.4)	1	(0.1)
Hyperhidrosis	5	(1.0)	0	(0.0)	5	(0.6)
Lipoatrophy	1	(0.2)	1	(0.4)	2	(0.3)
Lipodystrophy Acquired	7	(1.4)	2	(0.7)	9	(1.1)
Lipohypertrophy	3	(0.6)	1	(0.4)	4	(0.5)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	43	(8.5)	27	(9.6)	70	(8.9)
Night Sweats	5	(1.0)	3	(1.1)	8	(1.0)
Palmar Erythema	0	(0.0)	1	(0.4)	1	(0.1)
Prurigo	1	(0.2)	0	(0.0)	1	(0.1)
Pruritus	8	(1.6)	2	(0.7)	10	(1.3)
Pruritus Generalised	2	(0.4)	0	(0.0)	2	(0.3)
Rash	7	(1.4)	5	(1.8)	12	(1.5)
Rash Macular	1	(0.2)	1	(0.4)	2	(0.3)
Rash Maculo-Papular	3	(0.6)	1	(0.4)	4	(0.5)
Skin Hyperpigmentation	0	(0.0)	1	(0.4)	1	(0.1)
Skin Nodule	2	(0.4)	3	(1.1)	5	(0.6)
Subcutaneous Nodule	3	(0.6)	4	(1.4)	7	(0.9)
Systemic Lupus Erythematosus Rash	0	(0.0)	1	(0.4)	1	(0.1)
Xeroderma	1	(0.2)	0	(0.0)	1	(0.1)
Vascular Disorders	6	(1.2)	3	(1.1)	9	(1.1)
Flushing	1	(0.2)	0	(0.0)	1	(0.1)
Haematoma	2	(0.4)	3	(1.1)	5	(0.6)
Hot Flush	1	(0.2)	0	(0.0)	1	(0.1)
Hypertension	2	(0.4)	0	(0.0)	2	(0.3)

Although a patient may have had two or more drug-related clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005-Define, P018-Define, P019-Define]

Appendix 2.7.4: 22

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Patients With One Or More Drug-Related Adverse Experiences	242	(47.7)	146	(51.8)	388	(49.2)
Patients With No Drug-Related Adverse Experience	265	(52.3)	136	(48.2)	401	(50.8)
Blood And Lymphatic System Disorders	5	(1.0)	8	(2.8)	13	(1.6)
Anaemia	2	(0.4)	4	(1.4)	6	(0.8)
Anaemia Macrocytic	1	(0.2)	0	(0.0)	1	(0.1)
Iron Deficiency Anaemia	1	(0.2)	0	(0.0)	1	(0.1)
Lymphadenopathy	0	(0.0)	2	(0.7)	2	(0.3)
Neutropenia	2	(0.4)	2	(0.7)	4	(0.5)
Cardiac Disorders	3	(0.6)	2	(0.7)	5	(0.6)
Arrhythmia	0	(0.0)	1	(0.4)	1	(0.1)
Cardiovascular Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Myocardial Infarction	1	(0.2)	0	(0.0)	1	(0.1)
Palpitations	1	(0.2)	0	(0.0)	1	(0.1)
Ventricular Extrasystoles	1	(0.2)	0	(0.0)	1	(0.1)
Ear And Labyrinth Disorders	4	(0.8)	0	(0.0)	4	(0.5)
Vertigo	4	(0.8)	0	(0.0)	4	(0.5)
Eye Disorders	3	(0.6)	3	(1.1)	6	(0.8)
Conjunctival Hyperaemia	0	(0.0)	1	(0.4)	1	(0.1)
Eye Movement Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Lacrimation Increased	0	(0.0)	1	(0.4)	1	(0.1)
Ocular Icterus	1	(0.2)	0	(0.0)	1	(0.1)
Visual Acuity Reduced	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Eye Disorders	3	(0.6)	3	(1.1)	6	(0.8)
Visual Disturbance	1	(0.2)	0	(0.0)	1	(0.1)
Gastrointestinal Disorders	109	(21.5)	65	(23.0)	174	(22.1)
Abdominal Discomfort	3	(0.6)	0	(0.0)	3	(0.4)
Abdominal Distension	10	(2.0)	6	(2.1)	16	(2.0)
Abdominal Mass	1	(0.2)	0	(0.0)	1	(0.1)
Abdominal Pain	14	(2.8)	6	(2.1)	20	(2.5)
Abdominal Pain Upper	5	(1.0)	2	(0.7)	7	(0.9)
Anal Discomfort	1	(0.2)	0	(0.0)	1	(0.1)
Bowel Sounds Abnormal	0	(0.0)	1	(0.4)	1	(0.1)
Chapped Lips	1	(0.2)	0	(0.0)	1	(0.1)
Constipation	6	(1.2)	1	(0.4)	7	(0.9)
Defaecation Urgency	0	(0.0)	2	(0.7)	2	(0.3)
Diarrhoea	44	(8.7)	31	(11.0)	75	(9.5)
Dry Mouth	2	(0.4)	1	(0.4)	3	(0.4)
Dyspepsia	2	(0.4)	4	(1.4)	6	(0.8)
Eructation	1	(0.2)	1	(0.4)	2	(0.3)
Flatulence	11	(2.2)	5	(1.8)	16	(2.0)
Gastric Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Gastritis	1	(0.2)	2	(0.7)	3	(0.4)
Gastrointestinal Pain	2	(0.4)	0	(0.0)	2	(0.3)
Gastrooesophageal Reflux Disease	3	(0.6)	1	(0.4)	4	(0.5)
Glossitis	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Gastrointestinal Disorders	109	(21.5)	65	(23.0)	174	(22.1)
Hypoaesthesia Oral	0	(0.0)	1	(0.4)	1	(0.1)
Mouth Ulceration	0	(0.0)	1	(0.4)	1	(0.1)
Nausea	32	(6.3)	23	(8.2)	55	(7.0)
Odynophagia	1	(0.2)	0	(0.0)	1	(0.1)
Oral Pain	1	(0.2)	0	(0.0)	1	(0.1)
Pancreatitis	0	(0.0)	1	(0.4)	1	(0.1)
Pancreatitis Acute	1	(0.2)	0	(0.0)	1	(0.1)
Peptic Ulcer	1	(0.2)	0	(0.0)	1	(0.1)
Rectal Haemorrhage	1	(0.2)	0	(0.0)	1	(0.1)
Salivary Hypersecretion	0	(0.0)	1	(0.4)	1	(0.1)
Stomach Discomfort	1	(0.2)	1	(0.4)	2	(0.3)
Vomiting	13	(2.6)	13	(4.6)	26	(3.3)
General Disorders And Administration Site Conditions	98	(19.3)	48	(17.0)	146	(18.5)
Asthenia	8	(1.6)	2	(0.7)	10	(1.3)
Chest Discomfort	2	(0.4)	1	(0.4)	3	(0.4)
Chills	1	(0.2)	0	(0.0)	1	(0.1)
Drug Intolerance	0	(0.0)	1	(0.4)	1	(0.1)
Fatigue	14	(2.8)	4	(1.4)	18	(2.3)
Feeling Abnormal	0	(0.0)	2	(0.7)	2	(0.3)
Feeling Hot	1	(0.2)	0	(0.0)	1	(0.1)
Feeling Jittery	1	(0.2)	0	(0.0)	1	(0.1)
Inflammation	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
General Disorders And Administration Site Conditions	98	(19.3)	48	(17.0)	146	(18.5)
Influenza Like Illness	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Bruising	2	(0.4)	0	(0.0)	2	(0.3)
Injection Site Erythema	3	(0.6)	1	(0.4)	4	(0.5)
Injection Site Haemorrhage	2	(0.4)	0	(0.0)	2	(0.3)
Injection Site Induration	4	(0.8)	0	(0.0)	4	(0.5)
Injection Site Inflammation	1	(0.2)	1	(0.4)	2	(0.3)
Injection Site Irritation	1	(0.2)	0	(0.0)	1	(0.1)
Injection Site Nodule	5	(1.0)	4	(1.4)	9	(1.1)
Injection Site Pain	7	(1.4)	1	(0.4)	8	(1.0)
Injection Site Pruritus	1	(0.2)	1	(0.4)	2	(0.3)
Injection Site Reaction	44	(8.7)	27	(9.6)	71	(9.0)
Injection Site Swelling	4	(0.8)	0	(0.0)	4	(0.5)
Irritability	1	(0.2)	0	(0.0)	1	(0.1)
Malaise	0	(0.0)	1	(0.4)	1	(0.1)
Mass	1	(0.2)	0	(0.0)	1	(0.1)
Nodule	1	(0.2)	1	(0.4)	2	(0.3)
Oedema Peripheral	1	(0.2)	0	(0.0)	1	(0.1)
Pyrexia	5	(1.0)	6	(2.1)	11	(1.4)
Xerosis	1	(0.2)	0	(0.0)	1	(0.1)
Hepatobiliary Disorders	6	(1.2)	3	(1.1)	9	(1.1)
Cholestasis	0	(0.0)	1	(0.4)	1	(0.1)
Hepatitis	2	(0.4)	1	(0.4)	3	(0.4)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Hepatobiliary Disorders	6	(1.2)	3	(1.1)	9	(1.1)
Hepatomegaly	1	(0.2)	1	(0.4)	2	(0.3)
Jaundice	3	(0.6)	1	(0.4)	4	(0.5)
Immune System Disorders	3	(0.6)	1	(0.4)	4	(0.5)
Drug Hypersensitivity	2	(0.4)	0	(0.0)	2	(0.3)
Hypersensitivity	2	(0.4)	1	(0.4)	3	(0.4)
Infections And Infestations	11	(2.2)	2	(0.7)	13	(1.6)
Cellulitis	1	(0.2)	0	(0.0)	1	(0.1)
Erythema Induratum	0	(0.0)	1	(0.4)	1	(0.1)
Folliculitis	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Simplex	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Virus Infection	1	(0.2)	0	(0.0)	1	(0.1)
Herpes Zoster	2	(0.4)	0	(0.0)	2	(0.3)
Influenza	1	(0.2)	0	(0.0)	1	(0.1)
Molluscum Contagiosum	1	(0.2)	0	(0.0)	1	(0.1)
Nasopharyngitis	0	(0.0)	1	(0.4)	1	(0.1)
Paronychia	1	(0.2)	0	(0.0)	1	(0.1)
Pulpitis Dental	1	(0.2)	0	(0.0)	1	(0.1)
Skin Infection	1	(0.2)	0	(0.0)	1	(0.1)
Investigations	3	(0.6)	3	(1.1)	6	(0.8)
Electrocardiogram PR Prolongation	1	(0.2)	0	(0.0)	1	(0.1)
Weight Decreased	1	(0.2)	2	(0.7)	3	(0.4)
Weight Increased	1	(0.2)	1	(0.4)	2	(0.3)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Metabolism And Nutrition Disorders	21	(4.1)	11	(3.9)	32	(4.1)
Anorexia	1	(0.2)	2	(0.7)	3	(0.4)
Body Fat Disorder	1	(0.2)	0	(0.0)	1	(0.1)
Central Obesity	1	(0.2)	0	(0.0)	1	(0.1)
Decreased Appetite	6	(1.2)	4	(1.4)	10	(1.3)
Diabetes Mellitus	3	(0.6)	0	(0.0)	3	(0.4)
Dyslipidaemia	1	(0.2)	0	(0.0)	1	(0.1)
Facial Wasting	1	(0.2)	0	(0.0)	1	(0.1)
Hypercholesterolaemia	2	(0.4)	1	(0.4)	3	(0.4)
Hyperglycaemia	0	(0.0)	1	(0.4)	1	(0.1)
Hyperlactacidaemia	3	(0.6)	0	(0.0)	3	(0.4)
Hyperlipidaemia	1	(0.2)	0	(0.0)	1	(0.1)
Hypertriglyceridaemia	1	(0.2)	3	(1.1)	4	(0.5)
Increased Appetite	1	(0.2)	0	(0.0)	1	(0.1)
Lipomatosis	1	(0.2)	0	(0.0)	1	(0.1)
Musculoskeletal And Connective Tissue Disorders	14	(2.8)	4	(1.4)	18	(2.3)
Arthralgia	5	(1.0)	0	(0.0)	5	(0.6)
Back Pain	1	(0.2)	0	(0.0)	1	(0.1)
Muscle Hypertrophy	0	(0.0)	1	(0.4)	1	(0.1)
Muscle Spasms	1	(0.2)	1	(0.4)	2	(0.3)
Musculoskeletal Pain	1	(0.2)	0	(0.0)	1	(0.1)
Myalgia	2	(0.4)	2	(0.7)	4	(0.5)
Myositis	1	(0.2)	0	(0.0)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Musculoskeletal And Connective Tissue Disorders	14	(2.8)	4	(1.4)	18	(2.3)
Pain In Extremity	5	(1.0)	0	(0.0)	5	(0.6)
Tendonitis	1	(0.2)	0	(0.0)	1	(0.1)
Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)	1	(0.2)	0	(0.0)	1	(0.1)
Acrochordon	1	(0.2)	0	(0.0)	1	(0.1)
Nervous System Disorders	49	(9.7)	31	(11.0)	80	(10.1)
Ageusia	0	(0.0)	1	(0.4)	1	(0.1)
Allodynia	1	(0.2)	0	(0.0)	1	(0.1)
Dizziness	7	(1.4)	3	(1.1)	10	(1.3)
Dizziness Postural	1	(0.2)	0	(0.0)	1	(0.1)
Dysgeusia	5	(1.0)	3	(1.1)	8	(1.0)
Headache	24	(4.7)	16	(5.7)	40	(5.1)
Hypersomnia	1	(0.2)	0	(0.0)	1	(0.1)
Hypoaesthesia	2	(0.4)	1	(0.4)	3	(0.4)
Lacunar Infarction	0	(0.0)	1	(0.4)	1	(0.1)
Lethargy	1	(0.2)	0	(0.0)	1	(0.1)
Migraine	0	(0.0)	1	(0.4)	1	(0.1)
Neuropathy	2	(0.4)	1	(0.4)	3	(0.4)
Neuropathy Peripheral	2	(0.4)	1	(0.4)	3	(0.4)
Paraesthesia	1	(0.2)	2	(0.7)	3	(0.4)
Parosmia	0	(0.0)	1	(0.4)	1	(0.1)
Polyneuropathy	1	(0.2)	0	(0.0)	1	(0.1)
Radial Nerve Palsy	0	(0.0)	1	(0.4)	1	(0.1)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Nervous System Disorders	49	(9.7)	31	(11.0)	80	(10.1)
Somnolence	4	(0.8)	2	(0.7)	6	(0.8)
Syncope	1	(0.2)	1	(0.4)	2	(0.3)
Tension Headache	1	(0.2)	0	(0.0)	1	(0.1)
Transient Ischaemic Attack	0	(0.0)	1	(0.4)	1	(0.1)
Psychiatric Disorders	16	(3.2)	12	(4.3)	28	(3.5)
Abnormal Dreams	2	(0.4)	3	(1.1)	5	(0.6)
Anxiety	2	(0.4)	1	(0.4)	3	(0.4)
Depressed Mood	0	(0.0)	1	(0.4)	1	(0.1)
Depression	3	(0.6)	1	(0.4)	4	(0.5)
Initial Insomnia	0	(0.0)	1	(0.4)	1	(0.1)
Insomnia	7	(1.4)	4	(1.4)	11	(1.4)
Libido Decreased	0	(0.0)	1	(0.4)	1	(0.1)
Mental Disorder	0	(0.0)	1	(0.4)	1	(0.1)
Middle Insomnia	1	(0.2)	0	(0.0)	1	(0.1)
Restlessness	0	(0.0)	1	(0.4)	1	(0.1)
Sleep Disorder	2	(0.4)	0	(0.0)	2	(0.3)
Renal And Urinary Disorders	5	(1.0)	5	(1.8)	10	(1.3)
Dysuria	0	(0.0)	1	(0.4)	1	(0.1)
Nephrolithiasis	0	(0.0)	1	(0.4)	1	(0.1)
Nephropathy Toxic	1	(0.2)	0	(0.0)	1	(0.1)
Nephrotic Syndrome	1	(0.2)	0	(0.0)	1	(0.1)
Nocturia	1	(0.2)	1	(0.4)	2	(0.3)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Renal And Urinary Disorders	5	(1.0)	5	(1.8)	10	(1.3)
Pollakiuria	1	(0.2)	1	(0.4)	2	(0.3)
Renal Failure	1	(0.2)	0	(0.0)	1	(0.1)
Renal Impairment	1	(0.2)	0	(0.0)	1	(0.1)
Urinary Retention	0	(0.0)	1	(0.4)	1	(0.1)
Reproductive System And Breast Disorders	2	(0.4)	0	(0.0)	2	(0.3)
Erectile Dysfunction	1	(0.2)	0	(0.0)	1	(0.1)
Gynaecomastia	1	(0.2)	0	(0.0)	1	(0.1)
Respiratory, Thoracic And Mediastinal Disorders	4	(0.8)	0	(0.0)	4	(0.5)
Epistaxis	1	(0.2)	0	(0.0)	1	(0.1)
Nasal Congestion	1	(0.2)	0	(0.0)	1	(0.1)
Pharyngeal Erythema	1	(0.2)	0	(0.0)	1	(0.1)
Pharyngeal Ulceration	1	(0.2)	0	(0.0)	1	(0.1)
Skin And Subcutaneous Tissue Disorders	40	(7.9)	27	(9.6)	67	(8.5)
Alopecia	0	(0.0)	1	(0.4)	1	(0.1)
Dermatitis Acneiform	1	(0.2)	0	(0.0)	1	(0.1)
Dry Skin	1	(0.2)	0	(0.0)	1	(0.1)
Eczema	0	(0.0)	1	(0.4)	1	(0.1)
Erythema	1	(0.2)	0	(0.0)	1	(0.1)
Fat Atrophy	1	(0.2)	0	(0.0)	1	(0.1)
Hyperhidrosis	5	(1.0)	0	(0.0)	5	(0.6)
Lipoatrophy	1	(0.2)	1	(0.4)	2	(0.3)
Lipodystrophy Acquired	4	(0.8)	1	(0.4)	5	(0.6)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Skin And Subcutaneous Tissue Disorders	40	(7.9)	27	(9.6)	67	(8.5)
Lipohypertrophy	3	(0.6)	1	(0.4)	4	(0.5)
Night Sweats	5	(1.0)	3	(1.1)	8	(1.0)
Palmar Erythema	0	(0.0)	1	(0.4)	1	(0.1)
Prurigo	0	(0.0)	1	(0.4)	1	(0.1)
Pruritus	8	(1.6)	2	(0.7)	10	(1.3)
Pruritus Generalised	2	(0.4)	0	(0.0)	2	(0.3)
Rash	6	(1.2)	5	(1.8)	11	(1.4)
Rash Macular	1	(0.2)	1	(0.4)	2	(0.3)
Rash Maculo-Papular	2	(0.4)	1	(0.4)	3	(0.4)
Rash Papular	1	(0.2)	0	(0.0)	1	(0.1)
Seborrhoeic Dermatitis	1	(0.2)	0	(0.0)	1	(0.1)
Skin Hyperpigmentation	0	(0.0)	1	(0.4)	1	(0.1)
Skin Nodule	2	(0.4)	3	(1.1)	5	(0.6)
Subcutaneous Nodule	2	(0.4)	4	(1.4)	6	(0.8)
Xeroderma	1	(0.2)	0	(0.0)	1	(0.1)
Vascular Disorders	6	(1.2)	3	(1.1)	9	(1.1)
Flushing	1	(0.2)	0	(0.0)	1	(0.1)
Haematoma	2	(0.4)	3	(1.1)	5	(0.6)
Hot Flush	2	(0.4)	0	(0.0)	2	(0.3)

Number (%) of Patients With Specific Drug-Related (Overall) Clinical Adverse Experiences
(Incidence >0% in One or More Treatment Groups) by System Organ Class—
Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N = 507)		Placebo (N = 282)		Total (N = 789)	
	n	(%)	n	(%)	n	(%)
Vascular Disorders	6	(1.2)	3	(1.1)	9	(1.1)
Hypertension	1	(0.2)	0	(0.0)	1	(0.1)

Although a patient may have had two or more drug-related clinical adverse experiences, the patient is counted only once within a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

[Ref. 5.3.5.1: P005, P018, P019]

Appendix 2.7.4: 23

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Patients with one or more adverse experiences	109/507	(21.5)	55/282	(19.5)	164/789	(20.8)
Patients with no adverse experiences	398/507	(78.5)	227/282	(80.5)	625/789	(79.2)
Blood Chemistry Test	**92/507**	**(18.1)**	**41/282**	**(14.5)**	**133/789**	**(16.9)**
Alanine aminotransferase increased	24/507	(4.7)	6/282	(2.1)	30/789	(3.8)
Alkaline phosphatase increased	3/507	(0.6)	0/282	(0.0)	3/789	(0.4)
Aspartate aminotransferase increased	23/507	(4.5)	8/282	(2.8)	31/789	(3.9)
Blood albumin decreased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Blood amylase increased	3/507	(0.6)	0/282	(0.0)	3/789	(0.4)
Blood bilirubin increased	7/507	(1.4)	4/282	(1.4)	11/789	(1.4)
Blood bilirubin indirect increased	3/507	(0.6)	0/282	(0.0)	3/789	(0.4)
Blood cholesterol increased	14/507	(2.8)	6/279	(2.2)	20/786	(2.5)
Blood creatinine increased	10/507	(2.0)	5/282	(1.8)	15/789	(1.9)
Blood glucose increased	4/507	(0.8)	2/282	(0.7)	6/789	(0.8)
Blood lactic acid increased	2/7	(28.6)	0/1	(0.0)	2/8	(25.0)
Blood pancreatic amylase increased	2/61	(3.3)	1/27	(3.7)	3/88	(3.4)
Blood phosphorus decreased	4/507	(0.8)	6/282	(2.1)	10/789	(1.3)
Blood potassium decreased	1/507	(0.2)	1/282	(0.4)	2/789	(0.3)
Blood sodium decreased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Blood triglycerides increased	19/507	(3.7)	10/279	(3.6)	29/786	(3.7)
Blood urea nitrogen increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Creatine phosphokinase increased	19/507	(3.7)	3/282	(1.1)	22/789	(2.8)

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Blood Chemistry Test	**92/507**	**(18.1)**	**41/282**	**(14.5)**	**133/789**	**(16.9)**
Fasting blood glucose increased	4/507	(0.8)	2/280	(0.7)	6/787	(0.8)
High density lipoprotein increased	1/506	(0.2)	0/279	(0.0)	1/785	(0.1)
Lipase increased	9/507	(1.8)	2/282	(0.7)	11/789	(1.4)
Low density lipoprotein increased	4/475	(0.8)	1/265	(0.4)	5/740	(0.7)
Clinical Serology Test	**1/25**	**(4.0)**	**0/23**	**(0.0)**	**1/48**	**(2.1)**
Human papilloma virus antibody positive	1/1	(100.0)	0/†		1/1	(100.0)
Endocrine Test	**0/68**	**(0.0)**	**1/33**	**(3.0)**	**1/101**	**(1.0)**
Blood testosterone decreased	0/†		1/1	(100.0)	1/1	(100.0)
Hematology Laboratory Test	**15/507**	**(3.0)**	**12/282**	**(4.3)**	**27/789**	**(3.4)**
Absolute lymphocyte count decreased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Absolute neutrophil count decreased	3/507	(0.6)	4/282	(1.4)	7/789	(0.9)
Absolute neutrophil count increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
CD4 lymphocytes decreased	1/506	(0.2)	0/282	(0.0)	1/788	(0.1)
Haematocrit decreased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Haemoglobin decreased	2/507	(0.4)	2/282	(0.7)	4/789	(0.5)
Mean cell volume increased	2/507	(0.4)	0/282	(0.0)	2/789	(0.3)
Neutrophil count decreased	1/16	(6.3)	2/8	(25.0)	3/24	(12.5)
Platelet count decreased	6/506	(1.2)	2/282	(0.7)	8/788	(1.0)

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Hematology Laboratory Test	**15/507**	**(3.0)**	**12/282**	**(4.3)**	**27/789**	**(3.4)**
Red blood cell count decreased	2/507	(0.4)	0/282	(0.0)	2/789	(0.3)
White blood cell count decreased	1/507	(0.2)	3/282	(1.1)	4/789	(0.5)
White blood cell count increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Hemostatic Function Test	**3/507**	**(0.6)**	**2/282**	**(0.7)**	**5/789**	**(0.6)**
International normalised ratio increased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Prothrombin time prolonged	3/507	(0.6)	1/282	(0.4)	4/789	(0.5)
Urinalysis Test	**7/504**	**(1.4)**	**4/278**	**(1.4)**	**11/782**	**(1.4)**
Bacteria urine identified	1/193	(0.5)	0/101	(0.0)	1/294	(0.3)
Blood urine present	0/504	(0.0)	1/278	(0.4)	1/782	(0.1)
Glucose urine present	1/504	(0.2)	0/278	(0.0)	1/782	(0.1)
Protein urine present	3/504	(0.6)	3/278	(1.1)	6/782	(0.8)
Red blood cells urine positive	2/504	(0.4)	0/278	(0.0)	2/782	(0.3)

† indicates that there was no associated laboratory test or there were no patients for whom the laboratory test was recorded postbaseline.

Although a patient may have had two or more laboratory adverse experiences, the patient is counted only once in a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

n/m = Number of patients with laboratory adverse experiences / number of patients for whom the laboratory test was recorded postbaseline.

[Ref. 5.3.5.1: P005-Define, P018-Define, P019-Define]

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Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort - *Original Application*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Patients with one or more adverse experiences	99/507	(19.5)	51/282	(18.1)	150/789	(19.0)
Patients with no adverse experiences	408/507	(80.5)	231/282	(81.9)	639/789	(81.0)
Blood Chemistry Test	**84/507**	**(16.6)**	**39/282**	**(13.8)**	**123/789**	**(15.6)**
Alanine aminotransferase increased	23/507	(4.5)	6/282	(2.1)	29/789	(3.7)
Alkaline phosphatase increased	3/507	(0.6)	0/282	(0.0)	3/789	(0.4)
Aspartate aminotransferase increased	22/507	(4.3)	7/282	(2.5)	29/789	(3.7)
Blood albumin decreased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Blood amylase increased	2/507	(0.4)	0/282	(0.0)	2/789	(0.3)
Blood bilirubin increased	8/507	(1.6)	4/282	(1.4)	12/789	(1.5)
Blood bilirubin indirect increased	2/507	(0.4)	0/282	(0.0)	2/789	(0.3)
Blood cholesterol increased	11/507	(2.2)	4/279	(1.4)	15/786	(1.9)
Blood creatinine increased	7/507	(1.4)	6/282	(2.1)	13/789	(1.6)
Blood glucose increased	5/507	(1.0)	2/282	(0.7)	7/789	(0.9)
Blood lactic acid increased	1/7	(14.3)	0/1	(0.0)	1/8	(12.5)
Blood pancreatic amylase increased	2/58	(3.4)	1/27	(3.7)	3/85	(3.5)
Blood phosphorus decreased	4/507	(0.8)	6/282	(2.1)	10/789	(1.3)
Blood potassium decreased	1/507	(0.2)	1/282	(0.4)	2/789	(0.3)
Blood sodium decreased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Blood triglycerides increased	18/507	(3.6)	9/279	(3.2)	27/786	(3.4)
Blood urea nitrogen increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Creatine phosphokinase increased	16/507	(3.2)	2/282	(0.7)	18/789	(2.3)

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort - *Original Application*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Blood Chemistry Test	**84/507**	**(16.6)**	**39/282**	**(13.8)**	**123/789**	**(15.6)**
Fasting blood glucose increased	3/507	(0.6)	2/280	(0.7)	5/787	(0.6)
High density lipoprotein increased	1/506	(0.2)	0/277	(0.0)	1/783	(0.1)
Lipase increased	7/507	(1.4)	1/282	(0.4)	8/789	(1.0)
Low density lipoprotein increased	3/472	(0.6)	1/257	(0.4)	4/729	(0.5)
Clinical Serology Test	**1/23**	**(4.3)**	**0/20**	**(0.0)**	**1/43**	**(2.3)**
Human papilloma virus antibody positive	1/1	(100.0)	0/†		1/1	(100.0)
Endocrine Test	**0/68**	**(0.0)**	**1/33**	**(3.0)**	**1/101**	**(1.0)**
Blood testosterone decreased	0/†		1/1	(100.0)	1/1	(100.0)
Hematology Laboratory Test	**14/507**	**(2.8)**	**10/282**	**(3.5)**	**24/789**	**(3.0)**
Absolute lymphocyte count decreased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Absolute neutrophil count decreased	3/507	(0.6)	3/282	(1.1)	6/789	(0.8)
CD4 lymphocytes decreased	1/506	(0.2)	0/282	(0.0)	1/788	(0.1)
Haemoglobin decreased	1/507	(0.2)	2/282	(0.7)	3/789	(0.4)
Mean cell volume increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Neutrophil count decreased	1/14	(7.1)	1/8	(12.5)	2/22	(9.1)

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort - *Original Application*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Hematology Laboratory Test	**14/507**	**(2.8)**	**10/282**	**(3.5)**	**24/789**	**(3.0)**
Platelet count decreased	6/506	(1.2)	2/282	(0.7)	8/788	(1.0)
Red blood cell count decreased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
White blood cell count decreased	1/507	(0.2)	2/282	(0.7)	3/789	(0.4)
Hemostatic Function Test	**3/507**	**(0.6)**	**1/282**	**(0.4)**	**4/789**	**(0.5)**
International normalised ratio increased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Prothrombin time prolonged	3/507	(0.6)	0/282	(0.0)	3/789	(0.4)
Urinalysis Test	**7/504**	**(1.4)**	**4/278**	**(1.4)**	**11/782**	**(1.4)**
Bacteria urine identified	1/178	(0.6)	0/94	(0.0)	1/272	(0.4)
Blood urine present	0/504	(0.0)	1/278	(0.4)	1/782	(0.1)
Glucose urine present	2/504	(0.4)	0/278	(0.0)	2/782	(0.3)
Protein urine present	3/504	(0.6)	3/278	(1.1)	6/782	(0.8)
Red blood cells urine positive	3/504	(0.6)	0/278	(0.0)	3/782	(0.4)

† indicates that there was no associated laboratory test or there were no patients for whom the laboratory test was recorded postbaseline.

Although a patient may have had two or more laboratory adverse experiences, the patient is counted only once in a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

n/m = Number of patients with laboratory adverse experiences / number of patients for whom the laboratory test was recorded postbaseline.

[Ref. 5.3.5.1: P005, P018, P019]

Appendix 2.7.4: 25

Number (%) of Patients With Specific Drug-Related (Overall) Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Patients with one or more adverse experiences	66/507	(13.0)	33/282	(11.7)	99/789	(12.5)
Patients with no adverse experiences	441/507	(87.0)	249/282	(88.3)	690/789	(87.5)
Blood Chemistry Test	**60/507**	**(11.8)**	**26/282**	**(9.2)**	**86/789**	**(10.9)**
Alanine aminotransferase increased	16/507	(3.2)	2/282	(0.7)	18/789	(2.3)
Aspartate aminotransferase increased	13/507	(2.6)	3/282	(1.1)	16/789	(2.0)
Blood amylase increased	2/507	(0.4)	0/282	(0.0)	2/789	(0.3)
Blood bilirubin increased	6/507	(1.2)	4/282	(1.4)	10/789	(1.3)
Blood bilirubin indirect increased	3/507	(0.6)	0/282	(0.0)	3/789	(0.4)
Blood cholesterol increased	13/507	(2.6)	6/279	(2.2)	19/786	(2.4)
Blood creatinine increased	9/507	(1.8)	5/282	(1.8)	14/789	(1.8)
Blood glucose increased	1/507	(0.2)	2/282	(0.7)	3/789	(0.4)
Blood lactic acid increased	2/7	(28.6)	0/1	(0.0)	2/8	(25.0)
Blood pancreatic amylase increased	1/61	(1.6)	1/27	(3.7)	2/88	(2.3)
Blood phosphorus decreased	1/507	(0.2)	4/282	(1.4)	5/789	(0.6)
Blood sodium decreased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Blood triglycerides increased	15/507	(3.0)	4/279	(1.4)	19/786	(2.4)
Blood urea nitrogen increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Creatine phosphokinase increased	6/507	(1.2)	3/282	(1.1)	9/789	(1.1)
Fasting blood glucose increased	2/507	(0.4)	0/280	(0.0)	2/787	(0.3)
High density lipoprotein increased	1/506	(0.2)	0/279	(0.0)	1/785	(0.1)
Lipase increased	6/507	(1.2)	0/282	(0.0)	6/789	(0.8)

Number (%) of Patients With Specific Drug-Related (Overall) Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Blood Chemistry Test	**60/507**	**(11.8)**	**26/282**	**(9.2)**	**86/789**	**(10.9)**
Low density lipoprotein increased	4/475	(0.8)	1/265	(0.4)	5/740	(0.7)
Hematology Laboratory Test	**6/507**	**(1.2)**	**8/282**	**(2.8)**	**14/789**	**(1.8)**
Absolute lymphocyte count decreased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Absolute neutrophil count decreased	1/507	(0.2)	2/282	(0.7)	3/789	(0.4)
Haemoglobin decreased	1/507	(0.2)	2/282	(0.7)	3/789	(0.4)
Mean cell volume increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Neutrophil count decreased	0/16	(0.0)	1/8	(12.5)	1/24	(4.2)
Platelet count decreased	3/506	(0.6)	1/282	(0.4)	4/788	(0.5)
White blood cell count decreased	1/507	(0.2)	2/282	(0.7)	3/789	(0.4)
Urinalysis Test	**1/504**	**(0.2)**	**0/278**	**(0.0)**	**1/782**	**(0.1)**
Red blood cells urine positive	1/504	(0.2)	0/278	(0.0)	1/782	(0.1)

Although a patient may have had two or more drug-related laboratory adverse experiences, the patient is counted only once in a category. The same patient may appear in different categories.

Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).

Adverse experience terms are from MedDRA Version 9.1.

n/m = Number of patients with laboratory adverse experiences / number of patients for whom the laboratory test was recorded postbaseline.

[Ref. 5.3.5.1: P005-Define, P018-Define, P019-Define]

Appendix 2.7.4: 26

Number (%) of Patients With Specific Drug-Related (Overall) Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Patients with one or more drug-related adverse experiences	58/507	(11.4)	32/282	(11.3)	90/789	(11.4)
Patients with no drug-related adverse experiences	449/507	(88.6)	250/282	(88.7)	699/789	(88.6)
Blood Chemistry Test	**53/507**	**(10.5)**	**25/282**	**(8.9)**	**78/789**	**(9.9)**
Alanine aminotransferase increased	16/507	(3.2)	2/282	(0.7)	18/789	(2.3)
Aspartate aminotransferase increased	13/507	(2.6)	3/282	(1.1)	16/789	(2.0)
Blood amylase increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Blood bilirubin increased	6/507	(1.2)	4/282	(1.4)	10/789	(1.3)
Blood bilirubin indirect increased	2/507	(0.4)	0/282	(0.0)	2/789	(0.3)
Blood cholesterol increased	9/507	(1.8)	4/279	(1.4)	13/786	(1.7)
Blood creatinine increased	7/507	(1.4)	6/282	(2.1)	13/789	(1.6)
Blood glucose increased	2/507	(0.4)	2/282	(0.7)	4/789	(0.5)
Blood lactic acid increased	1/7	(14.3)	0/1	(0.0)	1/8	(12.5)
Blood pancreatic amylase increased	1/58	(1.7)	1/27	(3.7)	2/85	(2.4)
Blood phosphorus decreased	1/507	(0.2)	4/282	(1.4)	5/789	(0.6)
Blood sodium decreased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Blood triglycerides increased	13/507	(2.6)	3/279	(1.1)	16/786	(2.0)
Blood urea nitrogen increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Creatine phosphokinase increased	4/507	(0.8)	2/282	(0.7)	6/789	(0.8)
Fasting blood glucose increased	1/507	(0.2)	0/280	(0.0)	1/787	(0.1)
High density lipoprotein increased	1/506	(0.2)	0/277	(0.0)	1/783	(0.1)
Lipase increased	4/507	(0.8)	0/282	(0.0)	4/789	(0.5)

Number (%) of Patients With Specific Drug-Related (Overall) Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category—Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, and 019) - *Original Application*

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Blood Chemistry Test	**53/507**	**(10.5)**	**25/282**	**(8.9)**	**78/789**	**(9.9)**
Low density lipoprotein increased	3/472	(0.6)	1/257	(0.4)	4/729	(0.5)
Hematology Laboratory Test	**5/507**	**(1.0)**	**7/282**	**(2.5)**	**12/789**	**(1.5)**
Absolute lymphocyte count decreased	0/507	(0.0)	1/282	(0.4)	1/789	(0.1)
Absolute neutrophil count decreased	1/507	(0.2)	1/282	(0.4)	2/789	(0.3)
Haemoglobin decreased	1/507	(0.2)	2/282	(0.7)	3/789	(0.4)
Mean cell volume increased	1/507	(0.2)	0/282	(0.0)	1/789	(0.1)
Neutrophil count decreased	0/14	(0.0)	1/8	(12.5)	1/22	(4.5)
Platelet count decreased	2/506	(0.4)	1/282	(0.4)	3/788	(0.4)
White blood cell count decreased	1/507	(0.2)	1/282	(0.4)	2/789	(0.3)
Urinalysis Test	**2/504**	**(0.4)**	**0/278**	**(0.0)**	**2/782**	**(0.3)**
Glucose urine present	1/504	(0.2)	0/278	(0.0)	1/782	(0.1)
Protein urine present	1/504	(0.2)	0/278	(0.0)	1/782	(0.1)

Number (%) of Patients With Specific Laboratory Adverse Experiences (Incidence >0% in One or More Treatment Groups) by Laboratory Test Category - Overall Drug-Related - Treatment-Experienced MK-0518 400 mg b.i.d. Double-Blind Cohort (Protocols 005, 018, 019)
- Original Application

	MK-0518 400 mg b.i.d. (N=507)		Placebo (N=282)		Total (N=789)	
	n/m	(%)	n/m	(%)	n/m	(%)
Urinalysis Test	**2/504**	**(0.4)**	**0/278**	**(0.0)**	**2/782**	**(0.3)**
Red blood cells urine positive	2/504	(0.4)	0/278	(0.0)	2/782	(0.3)

Although a patient may have had two or more drug-related laboratory adverse experiences, the patient is counted only once in a category. The same patient may appear in different categories.
Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).
Adverse experience terms are from MedDRA Version 9.1.
n/m = Number of patients with laboratory adverse experiences / number of patients for whom the laboratory test was recorded postbaseline.

[Ref. 5.3.5.1: P005, P018, P019]

Appendix 2.7.4: 27

Clinical Adverse Experience Summary—Open-Label Post Virologic Failure
(Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Number (%) of patients:		
With one or more adverse experiences	153	(68.6)
With no adverse experience	70	(31.4)
With drug-related adverse experiences†	54	(24.2)
With serious adverse experiences	27	(12.1)
With serious drug-related adverse experiences	3	(1.3)
Who died	1	(0.4)
Discontinued due to adverse experiences	1	(0.4)
Discontinued due to drug-related adverse experiences	0	(0.0)
Discontinued due to serious adverse experiences	1	(0.4)
Discontinued due to serious drug-related adverse experiences	0	(0.0)
† Determined by the investigator to be possibly, probably or definitely drug-related.		
Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).		

[Ref. 5.3.5.1: P005-Define, P018-Define, P019-Define]

Appendix 2.7.4: 28

Clinical Adverse Experience Summary—Open-Label Post Virologic Failure
(Protocols 005, 018, and 019) - *Original Application*

	MK-0518 (N = 177)	
	n	(%)
Number (%) of patients:		
With one or more adverse experiences	100	(56.5)
With no adverse experience	77	(43.5)
With drug-related† adverse experiences	34	(19.2)
With serious adverse experiences	19	(10.7)
With serious drug-related adverse experiences	1	(0.6)
Who died	1	(0.6)
Discontinued due to adverse experiences	0	(0.0)
Discontinued due to drug-related adverse experiences	0	(0.0)
Discontinued due to serious adverse experiences	0	(0.0)
Discontinued due to serious drug-related adverse experiences	0	(0.0)
†Determined by the investigator to be possibly, probably or definitely drug-related.		
Note: MK-0518 and Placebo were administered with Optimized Background Therapy (OBT).		

[Ref. 5.3.5.1: P005, P018, P019]

Appendix 2.7.4: 29

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Patients With One Or More Adverse Experiences	153	(68.6)
Patients With No Adverse Experience	70	(31.4)
Blood And Lymphatic System Disorders	10	(4.5)
Anaemia	5	(2.2)
Bone Marrow Toxicity	1	(0.4)
Lymphadenitis	1	(0.4)
Lymphadenopathy	4	(1.8)
Neutropenia	2	(0.9)
Cardiac Disorders	3	(1.3)
Angina Unstable	1	(0.4)
Palpitations	1	(0.4)
Tachycardia	1	(0.4)
Ear And Labyrinth Disorders	1	(0.4)
Cerumen Impaction	1	(0.4)
Eye Disorders	6	(2.7)
Conjunctival Haemorrhage	1	(0.4)
Conjunctivitis	1	(0.4)
Eye Oedema	1	(0.4)
Eyelid Oedema	1	(0.4)
Lacrimation Increased	2	(0.9)
Photophobia	1	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Eye Disorders	6	(2.7)
Vision Blurred	1	(0.4)
Gastrointestinal Disorders	45	(20.2)
Abdominal Distension	1	(0.4)
Abdominal Pain	5	(2.2)
Abdominal Pain Upper	1	(0.4)
Anal Ulcer	1	(0.4)
Aphthous Stomatitis	1	(0.4)
Bowel Sounds Abnormal	1	(0.4)
Colitis	1	(0.4)
Constipation	3	(1.3)
Dental Caries	4	(1.8)
Diarrhoea	12	(5.4)
Dry Mouth	2	(0.9)
Duodenitis	1	(0.4)
Dyspepsia	4	(1.8)
Dysphagia	2	(0.9)
Faecal Incontinence	1	(0.4)
Flatulence	1	(0.4)
Food Poisoning	1	(0.4)
Gastrointestinal Haemorrhage	1	(0.4)
Gingival Ulceration	1	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Gastrointestinal Disorders	45	(20.2)
Gingivitis	4	(1.8)
Haematemesis	1	(0.4)
Leukoplakia Oral	1	(0.4)
Lip Ulceration	1	(0.4)
Nausea	6	(2.7)
Oesophageal Varices Haemorrhage	1	(0.4)
Oesophagitis	1	(0.4)
Oral Pain	1	(0.4)
Proctitis	1	(0.4)
Salivary Hypersecretion	1	(0.4)
Tongue Eruption	1	(0.4)
Toothache	1	(0.4)
Vomiting	7	(3.1)
General Disorders And Administration Site Conditions	40	(17.9)
Aplasia	1	(0.4)
Asthenia	2	(0.9)
Chest Pain	2	(0.9)
Chills	2	(0.9)
Cyst	1	(0.4)
Drug Intolerance	2	(0.9)
Face Oedema	1	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
General Disorders And Administration Site Conditions	40	(17.9)
Fatigue	6	(2.7)
Feeling Hot	1	(0.4)
Influenza Like Illness	2	(0.9)
Injection Site Erythema	1	(0.4)
Injection Site Nodule	1	(0.4)
Injection Site Reaction	4	(1.8)
Nodule	1	(0.4)
Oedema Peripheral	2	(0.9)
Pain	2	(0.9)
Pitting Oedema	2	(0.9)
Pyrexia	16	(7.2)
Thirst	1	(0.4)
Hepatobiliary Disorders	3	(1.3)
Cholecystitis Acute	1	(0.4)
Cholestasis	1	(0.4)
Cytolytic Hepatitis	1	(0.4)
Hepatomegaly	1	(0.4)
Hepatosplenomegaly	1	(0.4)
Hyperbilirubinaemia	1	(0.4)
Liver Tenderness	1	(0.4)
Portal Hypertension	1	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Immune System Disorders	6	(2.7)
Drug Hypersensitivity	2	(0.9)
Hypersensitivity	3	(1.3)
Immune Reconstitution Syndrome	1	(0.4)
Infections And Infestations	89	(39.9)
Abscess Limb	1	(0.4)
Acarodermatitis	1	(0.4)
Anogenital Warts	2	(0.9)
Arthritis Bacterial	1	(0.4)
Bronchitis	7	(3.1)
Bronchitis Acute	1	(0.4)
Bronchitis Bacterial	1	(0.4)
Candidiasis	1	(0.4)
Cellulitis	2	(0.9)
Conjunctivitis Viral	1	(0.4)
Cytomegalovirus Chorioretinitis	2	(0.9)
Folliculitis	4	(1.8)
Fungal Infection	1	(0.4)
Fungal Skin Infection	1	(0.4)
Furuncle	2	(0.9)
Gastroenteritis	5	(2.2)
Gastroenteritis Salmonella	1	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Infections And Infestations	89	(39.9)
Genital Candidiasis	1	(0.4)
Herpes Simplex	8	(3.6)
Herpes Zoster	4	(1.8)
Influenza	6	(2.7)
Localised Infection	2	(0.9)
Molluscum Contagiosum	2	(0.9)
Nasopharyngitis	9	(4.0)
Oesophageal Candidiasis	4	(1.8)
Onychomycosis	1	(0.4)
Oral Candidiasis	7	(3.1)
Oral Hairy Leukoplakia	1	(0.4)
Otitis Externa	1	(0.4)
Otitis Media	1	(0.4)
Paronychia	1	(0.4)
Parotitis	1	(0.4)
Pharyngitis	2	(0.9)
Pharyngitis Streptococcal	1	(0.4)
Pneumococcal Sepsis	1	(0.4)
Pneumocystis Jiroveci Pneumonia	1	(0.4)
Pneumonia	4	(1.8)
Pneumonia Klebsiella	1	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Infections And Infestations	89	(39.9)
Proctitis Herpes	1	(0.4)
Progressive Multifocal Leukoencephalopathy	1	(0.4)
Respiratory Tract Infection	3	(1.3)
Rhinitis	1	(0.4)
Sepsis	1	(0.4)
Septic Shock	1	(0.4)
Sinusitis	4	(1.8)
Sinusitis Aspergillus	1	(0.4)
Staphylococcal Abscess	1	(0.4)
Subcutaneous Abscess	2	(0.9)
Syphilis	3	(1.3)
Tinea Cruris	1	(0.4)
Tinea Infection	1	(0.4)
Tooth Abscess	2	(0.9)
Upper Respiratory Tract Infection	9	(4.0)
Urinary Tract Infection	2	(0.9)
Vaginal Candidiasis	1	(0.4)
Vaginitis Bacterial	1	(0.4)
Varicella	1	(0.4)
Viral Infection	2	(0.9)
Viral Sinusitis	1	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Infections And Infestations	89	(39.9)
Wound Infection	1	(0.4)
Injury, Poisoning And Procedural Complications	14	(6.3)
Accidental Overdose	1	(0.4)
Animal Bite	1	(0.4)
Arthropod Bite	2	(0.9)
Ear Canal Abrasion	1	(0.4)
Eye Penetration	1	(0.4)
Hand Fracture	2	(0.9)
Human Bite	1	(0.4)
Limb Injury	1	(0.4)
Skin Laceration	1	(0.4)
Thermal Burn	1	(0.4)
Wound	1	(0.4)
Wrist Fracture	1	(0.4)
Investigations	6	(2.7)
Blood Creatine Increased	1	(0.4)
Breath Sounds Abnormal	1	(0.4)
Carotid Pulse Increased	1	(0.4)
Lymph Node Palpable	1	(0.4)
Waist Circumference Increased	1	(0.4)
Weight Decreased	1	(0.4)

Number (%) of Patients With Specific Clinical Adverse Experiences (Incidence >0% in One or More Treatment Groups) by System Organ Class – Open-Label Post Virologic Failure (Protocols 005, 018, and 019) - *Cumulative Data*

	MK-0518 (N = 223)	
	n	(%)
Metabolism And Nutrition Disorders	12	(5.4)
Anorexia	2	(0.9)
Cachexia	1	(0.4)
Diabetes Mellitus	2	(0.9)
Facial Wasting	1	(0.4)
Failure To Thrive	1	(0.4)
Gout	2	(0.9)
Hyperlipidaemia	2	(0.9)
Hyperuricaemia	1	(0.4)
Hypophosphataemia	1	(0.4)
Polydipsia	1	(0.4)
Musculoskeletal And Connective Tissue Disorders	28	(12.6)
Arthralgia	3	(1.3)
Axillary Mass	1	(0.4)
Back Pain	5	(2.2)
Costochondritis	1	(0.4)
Flank Pain	1	(0.4)
Joint Swelling	1	(0.4)
Muscle Spasms	6	(2.7)
Myalgia	4	(1.8)
Neck Pain	1	(0.4)
Nodule On Extremity	1	(0.4)