表 2.7.6-6　副作用の内訳（RCP，As-treated 集団）

	AQP4-IgG sero+ N = 213		AQP4-IgG sero- N = 17		Total N = 230	
System Organ Class[a] Preferred Term (MedDRA version 21.0)	Placebo N = 52	MEDI551 N = 161	Placebo N = 4	MEDI551 N = 13	Placebo N = 56	MEDI551 N = 174
Subjects with at least one related event	13 (25.0%)	39 (24.2%)	1 (25.0%)	2 (15.4%)	14 (25.0%)	41 (23.6%)
Blood and lymphatic system disorders	0	7 (4.3%)	0	0	0	7 (4.0%)
Anaemia	0	3 (1.9%)	0	0	0	3 (1.7%)
Leukopenia	0	1 (0.6%)	0	0	0	1 (0.6%)
Lymphopenia	0	3 (1.9%)	0	0	0	3 (1.7%)
Neutropenia	0	3 (1.9%)	0	0	0	3 (1.7%)
Ear and labyrinth disorders	0	2 (1.2%)	0	0	0	2 (1.1%)
Ear pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Tinnitus	0	1 (0.6%)	0	0	0	1 (0.6%)
Vertigo	0	1 (0.6%)	0	0	0	1 (0.6%)
Eye disorders	0	1 (0.6%)	0	1 (7.7%)	0	2 (1.1%)
Eye inflammation	0	0	0	1 (7.7%)	0	1 (0.6%)
Eye pain	0	1 (0.6%)	0	0	0	1 (0.6%)
Vision blurred	0	0	0	1 (7.7%)	0	1 (0.6%)
Gastrointestinal disorders	2 (3.8%)	5 (3.1%)	0	0	2 (3.6%)	5 (2.9%)
Diarrhoea	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Nausea	1 (1.9%)	4 (2.5%)	0	0	1 (1.8%)	4 (2.3%)
General disorders and administration site conditions	0	3 (1.9%)	0	0	0	3 (1.7%)
Chills	0	1 (0.6%)	0	0	0	1 (0.6%)
Fatigue	0	1 (0.6%)	0	0	0	1 (0.6%)
Oedema peripheral	0	1 (0.6%)	0	0	0	1 (0.6%)
Hepatobiliary disorders	1 (1.9%)	0	0	0	1 (1.8%)	0
Hepatitis	1 (1.9%)	0	0	0	1 (1.8%)	0
Infections and infestations	3 (5.8%)	7 (4.3%)	0	0	3 (5.4%)	7 (4.0%)
Atypical pneumonia	0	1 (0.6%)	0	0	0	1 (0.6%)
Bronchitis	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Herpes zoster	1 (1.9%)	0	0	0	1 (1.8%)	0
Hordeolum	0	1 (0.6%)	0	0	0	1 (0.6%)
Nasopharyngitis	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Oral herpes	1 (1.9%)	0	0	0	1 (1.8%)	0
Otitis externa	0	1 (0.6%)	0	0	0	1 (0.6%)
Salpingitis	0	1 (0.6%)	0	0	0	1 (0.6%)
Upper respiratory tract infection	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Urinary tract infection	0	2 (1.2%)	0	0	0	2 (1.1%)
Injury, poisoning and procedural complications	5 (9.6%)	14 (8.7%)	1 (25.0%)	1 (7.7%)	6 (10.7%)	15 (8.6%)
Infusion related reaction	5 (9.6%)	14 (8.7%)	1 (25.0%)	1 (7.7%)	6 (10.7%)	15 (8.6%)
Investigations	2 (3.8%)	4 (2.5%)	0	0	2 (3.6%)	4 (2.3%)
Alanine aminotransferase increased	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Aspartate aminotransferase increased	1 (1.9%)	0	0	0	1 (1.8%)	0
Blood bilirubin increased	1 (1.9%)	0	0	0	1 (1.8%)	0
Eosinophil percentage increased	0	1 (0.6%)	0	0	0	1 (0.6%)
Gamma-glutamyltransferase increased	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Liver function test increased	0	1 (0.6%)	0	0	0	1 (0.6%)
Lymphocyte count decreased	0	1 (0.6%)	0	0	0	1 (0.6%)
Lymphocyte count increased	1 (1.9%)	0	0	0	1 (1.8%)	0

表 2.7.6-6　副作用の内訳（RCP，As-treated 集団）（続き）

	AQP4-IgG sero+ N = 213		AQP4-IgG sero- N = 17		Total N = 230	
System Organ Class[a] Preferred Term (MedDRA version 21.0)	Placebo N = 52	MEDI551 N = 161	Placebo N = 4	MEDI551 N = 13	Placebo N = 56	MEDI551 N = 174
Neutrophil count increased	1 (1.9%)	0	0	0	1 (1.8%)	0
Metabolism and nutrition disorders	0	1 (0.6%)	0	1 (7.7%)	0	2 (1.1%)
Hypercholesterolaemia	0	1 (0.6%)	0	0	0	1 (0.6%)
Hypertriglyceridaemia	0	0	0	1 (7.7%)	0	1 (0.6%)
Musculoskeletal and connective tissue disorders	2 (3.8%)	2 (1.2%)	0	0	2 (3.6%)	2 (1.1%)
Arthralgia	1 (1.9%)	2 (1.2%)	0	0	1 (1.8%)	2 (1.1%)
Myalgia	1 (1.9%)	0	0	0	1 (1.8%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.6%)	0	0	0	1 (0.6%)
Pituitary tumour benign	0	1 (0.6%)	0	0	0	1 (0.6%)
Nervous system disorders	1 (1.9%)	3 (1.9%)	0	0	1 (1.8%)	3 (1.7%)
Dizziness	0	1 (0.6%)	0	0	0	1 (0.6%)
Headache	0	3 (1.9%)	0	0	0	3 (1.7%)
Hypertonia	1 (1.9%)	0	0	0	1 (1.8%)	0
Psychiatric disorders	0	1 (0.6%)	0	0	0	1 (0.6%)
Insomnia	0	1 (0.6%)	0	0	0	1 (0.6%)
Renal and urinary disorders	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Dysuria	1 (1.9%)	0	0	0	1 (1.8%)	0
Nocturia	0	1 (0.6%)	0	0	0	1 (0.6%)
Skin and subcutaneous tissue disorders	3 (5.8%)	7 (4.3%)	0	0	3 (5.4%)	7 (4.0%)
Blister	0	1 (0.6%)	0	0	0	1 (0.6%)
Dry skin	0	1 (0.6%)	0	0	0	1 (0.6%)
Night sweats	0	1 (0.6%)	0	0	0	1 (0.6%)
Pruritus	2 (3.8%)	0	0	0	2 (3.6%)	0
Rash	0	2 (1.2%)	0	0	0	2 (1.1%)
Rash maculo-papular	0	1 (0.6%)	0	0	0	1 (0.6%)
Urticaria	1 (1.9%)	1 (0.6%)	0	0	1 (1.8%)	1 (0.6%)
Vascular disorders	1 (1.9%)	0	0	0	1 (1.8%)	0
Hypertension	1 (1.9%)	0	0	0	1 (1.8%)	0

MEDI551 = Inebilizumab.
As-Treated 集団は少なくとも治験薬が 1 回投与された被験者とした.
a 被験者は事象の回数にかかわらず，SOC 及び PT 別に 1 件として計上した.
Source: Table 14.3.1.2.7.1，1155 CSR.

表 2.7.6-7　TEAE の内訳（OLP，Open-label 集団）

System Organ Class[a] Preferred Term (MedDRA version 21.0)	AQP4-IgG sero+ N = 198 Placebo/ MEDI551 N = 47	 MEDI551/ MEDI551 N = 151	AQP4-IgG sero- N = 15 Placebo/ MEDI551 N = 4	 MEDI551/ MEDI551 N = 11	Total N = 213 Placebo/ MEDI551 N = 51	 MEDI551/ MEDI551 N = 162
Subjects with at least one event	34 (72.3%)	98 (64.9%)	3 (75.0%)	10 (90.9%)	37 (72.5%)	108 (66.7%)
***not Coded Yet	0	1 (0.7%)	0	0	0	1 (0.6%)
***not Coded Yet	0	1 (0.7%)	0	0	0	1 (0.6%)
Blood and lymphatic system disorders	3 (6.4%)	2 (1.3%)	0	0	3 (5.9%)	2 (1.2%)
Anaemia	0	1 (0.7%)	0	0	0	1 (0.6%)
Iron deficiency anaemia	1 (2.1%)	0	0	0	1 (2.0%)	0
Lymphadenopathy	1 (2.1%)	0	0	0	1 (2.0%)	0
Neutropenia	1 (2.1%)	0	0	0	1 (2.0%)	0
Thrombocytosis	0	1 (0.7%)	0	0	0	1 (0.6%)
Cardiac disorders	0	5 (3.3%)	0	0	0	5 (3.1%)
Bradycardia	0	1 (0.7%)	0	0	0	1 (0.6%)
Cyanosis	0	1 (0.7%)	0	0	0	1 (0.6%)
Diastolic dysfunction	0	1 (0.7%)	0	0	0	1 (0.6%)
Left ventricular hypertrophy	0	1 (0.7%)	0	0	0	1 (0.6%)
Mitral valve incompetence	0	1 (0.7%)	0	0	0	1 (0.6%)
Palpitations	0	1 (0.7%)	0	0	0	1 (0.6%)
Supraventricular extrasystoles	0	1 (0.7%)	0	0	0	1 (0.6%)
Supraventricular tachycardia	0	1 (0.7%)	0	0	0	1 (0.6%)
Tricuspid valve incompetence	0	1 (0.7%)	0	0	0	1 (0.6%)
Ventricular extrasystoles	0	1 (0.7%)	0	0	0	1 (0.6%)
Congenital, familial and genetic disorders	0	1 (0.7%)	0	0	0	1 (0.6%)
Corneal dystrophy	0	1 (0.7%)	0	0	0	1 (0.6%)
Ear and labyrinth disorders	1 (2.1%)	5 (3.3%)	1 (25.0%)	0	2 (3.9%)	5 (3.1%)
Deafness unilateral	0	1 (0.7%)	0	0	0	1 (0.6%)
Ear pain	1 (2.1%)	0	0	0	1 (2.0%)	0
Hypoacusis	0	1 (0.7%)	0	0	0	1 (0.6%)
Meniere's disease	0	1 (0.7%)	0	0	0	1 (0.6%)
Tinnitus	0	1 (0.7%)	1 (25.0%)	0	1 (2.0%)	1 (0.6%)
Vertigo	0	1 (0.7%)	0	0	0	1 (0.6%)
Vertigo positional	0	2 (1.3%)	0	0	0	2 (1.2%)
Endocrine disorders	0	2 (1.3%)	0	0	0	2 (1.2%)
Hyperandrogenism	0	1 (0.7%)	0	0	0	1 (0.6%)
Steroid withdrawal syndrome	0	1 (0.7%)	0	0	0	1 (0.6%)
Eye disorders	6 (12.8%)	13 (8.6%)	1 (25.0%)	1 (9.1%)	7 (13.7%)	14 (8.6%)
Abnormal sensation in eye	0	1 (0.7%)	0	0	0	1 (0.6%)
Blindness unilateral	0	1 (0.7%)	0	0	0	1 (0.6%)
Cataract	0	2 (1.3%)	0	0	0	2 (1.2%)
Dacryostenosis acquired	0	1 (0.7%)	0	0	0	1 (0.6%)
Dry eye	4 (8.5%)	2 (1.3%)	0	1 (9.1%)	4 (7.8%)	3 (1.9%)
Eye irritation	0	2 (1.3%)	0	0	0	2 (1.2%)
Eye pain	2 (4.3%)	3 (2.0%)	1 (25.0%)	0	3 (5.9%)	3 (1.9%)
Eye pruritus	0	2 (1.3%)	0	0	0	2 (1.2%)
Foreign body sensation in eyes	0	1 (0.7%)	0	0	0	1 (0.6%)
Ocular discomfort	0	1 (0.7%)	0	0	0	1 (0.6%)
Ocular hyperaemia	0	1 (0.7%)	0	0	0	1 (0.6%)
Vision blurred	0	3 (2.0%)	0	0	0	3 (1.9%)
Vitreous floaters	0	1 (0.7%)	0	0	0	1 (0.6%)
Gastrointestinal disorders	14 (29.8%)	20 (13.2%)	0	4 (36.4%)	14 (27.5%)	24 (14.8%)
Abdominal discomfort	0	2 (1.3%)	0	0	0	2 (1.2%)
Abdominal distension	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Abdominal pain	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Abdominal pain lower	0	2 (1.3%)	0	0	0	2 (1.2%)
Abdominal pain upper	2 (4.3%)	1 (0.7%)	0	1 (9.1%)	2 (3.9%)	2 (1.2%)
Anal incontinence	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Chronic gastritis	0	1 (0.7%)	0	0	0	1 (0.6%)
Constipation	4 (8.5%)	3 (2.0%)	0	0	4 (7.8%)	3 (1.9%)
Dental plaque	0	1 (0.7%)	0	0	0	1 (0.6%)
Diarrhoea	3 (6.4%)	3 (2.0%)	0	2 (18.2%)	3 (5.9%)	5 (3.1%)

表 2.7.6-7　TEAE の内訳（OLP，Open-label 集団）（続き）

System Organ Class[a] Preferred Term (MedDRA version 21.0)	AQP4-IgG sero+ N = 198 Placebo/ MEDI551 N = 47	 MEDI551/ MEDI551 N = 151	AQP4-IgG sero- N = 15 Placebo/ MEDI551 N = 4	 MEDI551/ MEDI551 N = 11	Total N = 213 Placebo/ MEDI551 N = 51	 MEDI551/ MEDI551 N = 162
Dry mouth	0	1 (0.7%)	0	0	0	1 (0.6%)
Dyspepsia	0	1 (0.7%)	0	1 (9.1%)	0	2 (1.2%)
Gastric ulcer	0	1 (0.7%)	0	0	0	1 (0.6%)
Gastritis	1 (2.1%)	2 (1.3%)	0	0	1 (2.0%)	2 (1.2%)
Gastrooesophageal reflux disease	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Haemorrhoids	0	1 (0.7%)	0	0	0	1 (0.6%)
Nausea	3 (6.4%)	4 (2.6%)	0	0	3 (5.9%)	4 (2.5%)
Noninfective gingivitis	0	1 (0.7%)	0	0	0	1 (0.6%)
Oesophageal pain	0	1 (0.7%)	0	0	0	1 (0.6%)
Sensitivity of teeth	1 (2.1%)	0	0	0	1 (2.0%)	0
Stomatitis	1 (2.1%)	0	0	0	1 (2.0%)	0
Tooth deposit	0	1 (0.7%)	0	0	0	1 (0.6%)
Tooth impacted	0	0	0	1 (9.1%)	0	1 (0.6%)
Toothache	0	1 (0.7%)	0	1 (9.1%)	0	2 (1.2%)
Umbilical hernia	0	1 (0.7%)	0	0	0	1 (0.6%)
Vomiting	0	2 (1.3%)	0	1 (9.1%)	0	3 (1.9%)
General disorders and administration site conditions	8 (17.0%)	17 (11.3%)	1 (25.0%)	3 (27.3%)	9 (17.6%)	20 (12.3%)
Adverse drug reaction	0	1 (0.7%)	0	0	0	1 (0.6%)
Application site burn	0	1 (0.7%)	0	0	0	1 (0.6%)
Asthenia	0	2 (1.3%)	0	0	0	2 (1.2%)
Chills	0	0	0	1 (9.1%)	0	1 (0.6%)
Discomfort	1 (2.1%)	0	0	0	1 (2.0%)	0
Face oedema	0	1 (0.7%)	0	0	0	1 (0.6%)
Facial pain	0	1 (0.7%)	0	0	0	1 (0.6%)
Fatigue	0	6 (4.0%)	0	0	0	6 (3.7%)
Gait disturbance	1 (2.1%)	0	0	1 (9.1%)	1 (2.0%)	1 (0.6%)
Influenza like illness	2 (4.3%)	1 (0.7%)	0	0	2 (3.9%)	1 (0.6%)
Infusion site pain	0	1 (0.7%)	0	0	0	1 (0.6%)
Non-cardiac chest pain	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Oedema	1 (2.1%)	0	0	0	1 (2.0%)	0
Oedema peripheral	0	1 (0.7%)	0	1 (9.1%)	0	2 (1.2%)
Pain	1 (2.1%)	0	0	0	1 (2.0%)	0
Peripheral swelling	0	1 (0.7%)	0	0	0	1 (0.6%)
Pyrexia	1 (2.1%)	3 (2.0%)	1 (25.0%)	0	2 (3.9%)	3 (1.9%)
Thirst	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Hepatobiliary disorders	0	2 (1.3%)	0	0	0	2 (1.2%)
Cholelithiasis	0	1 (0.7%)	0	0	0	1 (0.6%)
Hepatic steatosis	0	1 (0.7%)	0	0	0	1 (0.6%)
Hepatotoxicity	0	1 (0.7%)	0	0	0	1 (0.6%)
Immune system disorders	0	2 (1.3%)	0	0	0	2 (1.2%)
Hypersensitivity	0	2 (1.3%)	0	0	0	2 (1.2%)
Immunosuppression	0	1 (0.7%)	0	0	0	1 (0.6%)
Infections and infestations	24 (51.1%)	62 (41.1%)	2 (50.0%)	3 (27.3%)	26 (51.0%)	65 (40.1%)
Abscess bacterial	1 (2.1%)	0	0	0	1 (2.0%)	0
Acarodermatitis	1 (2.1%)	0	0	0	1 (2.0%)	0
Acute sinusitis	1 (2.1%)	0	0	0	1 (2.0%)	0
Appendicitis	0	1 (0.7%)	0	0	0	1 (0.6%)
Atypical pneumonia	1 (2.1%)	0	0	0	1 (2.0%)	0
Bacterial vaginosis	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Bacteriuria	0	1 (0.7%)	0	0	0	1 (0.6%)
Bronchiolitis	0	1 (0.7%)	0	0	0	1 (0.6%)
Bronchitis	2 (4.3%)	4 (2.6%)	0	1 (9.1%)	2 (3.9%)	5 (3.1%)
Bronchitis bacterial	1 (2.1%)	0	0	0	1 (2.0%)	0
Cellulitis	0	1 (0.7%)	0	0	0	1 (0.6%)
Central nervous system infection	0	1 (0.7%)	0	0	0	1 (0.6%)
Chorioretinitis	0	1 (0.7%)	0	0	0	1 (0.6%)
Conjunctivitis	1 (2.1%)	2 (1.3%)	0	0	1 (2.0%)	2 (1.2%)
Cystitis	0	2 (1.3%)	0	0	0	2 (1.2%)
Folliculitis	1 (2.1%)	0	0	0	1 (2.0%)	0
Fungal infection	0	2 (1.3%)	0	0	0	2 (1.2%)
Gastrointestinal candidiasis	0	1 (0.7%)	0	0	0	1 (0.6%)

表 2.7.6-7　TEAE の内訳（OLP，Open-label 集団）（続き）

System Organ Class[a] Preferred Term (MedDRA version 21.0)	AQP4-IgG sero+ N = 198		AQP4-IgG sero- N = 15		Total N = 213	
	Placebo/ MEDI551 N = 47	MEDI551/ MEDI551 N = 151	Placebo/ MEDI551 N = 4	MEDI551/ MEDI551 N = 11	Placebo/ MEDI551 N = 51	MEDI551/ MEDI551 N = 162
Gingivitis	1 (2.1%)	0	0	0	1 (2.0%)	0
Herpes zoster	0	3 (2.0%)	0	0	0	3 (1.9%)
Incision site abscess	0	1 (0.7%)	0	0	0	1 (0.6%)
Influenza	2 (4.3%)	9 (6.0%)	0	0	2 (3.9%)	9 (5.6%)
Lower respiratory tract infection bacterial	0	1 (0.7%)	0	0	0	1 (0.6%)
Lower respiratory tract infection fungal	0	1 (0.7%)	0	0	0	1 (0.6%)
Nasopharyngitis	3 (6.4%)	16 (10.6%)	1 (25.0%)	1 (9.1%)	4 (7.8%)	17 (10.5%)
Oral fungal infection	0	1 (0.7%)	0	0	0	1 (0.6%)
Oral herpes	0	1 (0.7%)	0	0	0	1 (0.6%)
Otitis media	0	1 (0.7%)	0	0	0	1 (0.6%)
Papilloma viral infection	0	1 (0.7%)	0	0	0	1 (0.6%)
Paronychia	1 (2.1%)	0	0	0	1 (2.0%)	0
Periodontitis	1 (2.1%)	0	0	0	1 (2.0%)	0
Pharyngitis	1 (2.1%)	2 (1.3%)	0	0	1 (2.0%)	2 (1.2%)
Pharyngitis streptococcal	0	1 (0.7%)	0	0	0	1 (0.6%)
Pharyngotonsillitis	1 (2.1%)	0	0	0	1 (2.0%)	0
Pneumonia	0	2 (1.3%)	0	0	0	2 (1.2%)
Progressive multifocal leukoencephalopathy	0	1 (0.7%)	0	0	0	1 (0.6%)
Pyelonephritis	1 (2.1%)	0	0	0	1 (2.0%)	0
Pyelonephritis chronic	1 (2.1%)	0	0	0	1 (2.0%)	0
Pyuria	0	1 (0.7%)	0	0	0	1 (0.6%)
Renal abscess	0	1 (0.7%)	0	0	0	1 (0.6%)
Respiratory tract infection	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Respiratory tract infection viral	0	1 (0.7%)	0	0	0	1 (0.6%)
Rhinitis	0	1 (0.7%)	0	0	0	1 (0.6%)
Sepsis	0	1 (0.7%)	0	0	0	1 (0.6%)
Sinusitis	0	2 (1.3%)	0	0	0	2 (1.2%)
Subcutaneous abscess	1 (2.1%)	0	0	0	1 (2.0%)	0
Tonsillitis	0	1 (0.7%)	0	0	0	1 (0.6%)
Tonsillitis bacterial	0	1 (0.7%)	0	0	0	1 (0.6%)
Tooth abscess	0	1 (0.7%)	0	1 (9.1%)	0	2 (1.2%)
Tooth infection	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Tracheobronchitis	1 (2.1%)	0	0	0	1 (2.0%)	0
Upper respiratory tract infection	3 (6.4%)	11 (7.3%)	0	0	3 (5.9%)	11 (6.8%)
Urinary tract infection	13 (27.7%)	17 (11.3%)	0	1 (9.1%)	13 (25.5%)	18 (11.1%)
Vaginal infection	2 (4.3%)	3 (2.0%)	0	0	2 (3.9%)	3 (1.9%)
Viral infection	0	0	1 (25.0%)	0	1 (2.0%)	0
Viral rhinitis	0	1 (0.7%)	0	0	0	1 (0.6%)
Viral upper respiratory tract infection	1 (2.1%)	0	0	0	1 (2.0%)	0
Vulvovaginal mycotic infection	0	1 (0.7%)	0	0	0	1 (0.6%)
Wound infection	0	1 (0.7%)	0	0	0	1 (0.6%)
Injury, poisoning and procedural complications	14 (29.8%)	16 (10.6%)	0	4 (36.4%)	14 (27.5%)	20 (12.3%)
Animal bite	0	0	0	1 (9.1%)	0	1 (0.6%)
Concussion	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Contusion	1 (2.1%)	0	0	0	1 (2.0%)	0
Face injury	0	1 (0.7%)	0	0	0	1 (0.6%)
Facial bones fracture	0	1 (0.7%)	0	0	0	1 (0.6%)
Fall	0	5 (3.3%)	0	0	0	5 (3.1%)
Foot fracture	0	1 (0.7%)	0	0	0	1 (0.6%)
Incision site haematoma	0	1 (0.7%)	0	0	0	1 (0.6%)
Infusion related reaction	6 (12.8%)	6 (4.0%)	0	2 (18.2%)	6 (11.8%)	8 (4.9%)
Intentional product misuse	0	0	0	1 (9.1%)	0	1 (0.6%)
Laceration	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Ligament sprain	0	3 (2.0%)	0	2 (18.2%)	0	5 (3.1%)
Limb injury	2 (4.3%)	0	0	0	2 (3.9%)	0
Limb traumatic amputation	0	1 (0.7%)	0	0	0	1 (0.6%)
Muscle strain	1 (2.1%)	0	0	0	1 (2.0%)	0
Nail injury	2 (4.3%)	0	0	0	2 (3.9%)	0
Post-traumatic pain	0	0	0	1 (9.1%)	0	1 (0.6%)
Road traffic accident	0	0	0	1 (9.1%)	0	1 (0.6%)
Thermal burn	1 (2.1%)	0	0	0	1 (2.0%)	0
Tibia fracture	0	1 (0.7%)	0	0	0	1 (0.6%)
Tooth fracture	1 (2.1%)	1 (0.7%)	0	0	1 (2.0%)	1 (0.6%)
Wrist fracture	0	1 (0.7%)	0	0	0	1 (0.6%)