

**Table 6. Incidence of Related Treatment-Emergent Adverse Events
By System Organ Class and Preferred Term
Safety Population
(Based on the 09JAN2015 Data Transfer)**

System Organ Class Preferred Term	Total (N = 129)
Number of Subjects With Any Related TEAE	108 (83.7%)
Gastrointestinal disorders	69 (53.5%)
Nausea	50 (38.8%)
Vomiting	31 (24.0%)
Diarrhoea	17 (13.2%)
Constipation	9 (7.0%)
Abdominal pain	4 (3.1%)
Abdominal pain upper	3 (2.3%)
Dyspepsia	3 (2.3%)
Stomatitis	3 (2.3%)
Dry mouth	2 (1.6%)
Abdominal discomfort	1 (0.8%)
Abdominal distension	1 (0.8%)
Defaecation urgency	1 (0.8%)
Dysphagia	1 (0.8%)
Epigastric discomfort	1 (0.8%)
Eructation	1 (0.8%)
Oesophagitis	1 (0.8%)
Paraesthesia oral	1 (0.8%)
Salivary hypersecretion	1 (0.8%)
General disorders and administration site conditions	65 (50.4%)
Fatigue	37 (28.7%)
Infusion site pain	16 (12.4%)
Pyrexia	15 (11.6%)
Chills	9 (7.0%)
Asthenia	4 (3.1%)
Pain	4 (3.1%)
Infusion site reaction	3 (2.3%)
Oedema peripheral	3 (2.3%)
Extravasation	2 (1.6%)
Injection site pain	2 (1.6%)

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Mucosal inflammation	2 (1.6%)
Chest pain	1 (0.8%)
Face oedema	1 (0.8%)
Feeling of body temperature change	1 (0.8%)
General physical health deterioration	1 (0.8%)
Infusion site coldness	1 (0.8%)
Infusion site extravasation	1 (0.8%)
Infusion site inflammation	1 (0.8%)
Injection site induration	1 (0.8%)
Injection site inflammation	1 (0.8%)
Injection site phlebitis	1 (0.8%)
Injection site pruritus	1 (0.8%)
Malaise	1 (0.8%)
Oedema	1 (0.8%)
Thrombosis in device	1 (0.8%)
Blood and lymphatic system disorders	35 (27.1%)
Anaemia	16 (12.4%)
Thrombocytopenia	14 (10.9%)
Neutropenia	8 (6.2%)
Leukopenia	7 (5.4%)
Febrile neutropenia	4 (3.1%)
Lymphopenia	4 (3.1%)
Haemolytic anaemia	1 (0.8%)
Pancytopenia	1 (0.8%)
Thrombocytosis	1 (0.8%)
Investigations	34 (26.4%)
Electrocardiogram QT prolonged	13 (10.1%)
Alanine aminotransferase increased	6 (4.7%)
Aspartate aminotransferase increased	6 (4.7%)
Blood creatinine increased	5 (3.9%)
Weight decreased	4 (3.1%)

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Platelet count decreased	3 (2.3%)
Gamma-glutamyltransferase increased	2 (1.6%)
International normalised ratio increased	2 (1.6%)
Neutrophil count decreased	2 (1.6%)
Blood alkaline phosphatase increased	1 (0.8%)
Blood bilirubin increased	1 (0.8%)
Blood glucose increased	1 (0.8%)
Blood lactate dehydrogenase increased	1 (0.8%)
Blood potassium decreased	1 (0.8%)
Blood urea increased	1 (0.8%)
C-reactive protein increased	1 (0.8%)
Electrocardiogram ST segment depression	1 (0.8%)
Glomerular filtration rate decreased	1 (0.8%)
Liver function test abnormal	1 (0.8%)
Mean cell volume increased	1 (0.8%)
Prothrombin time shortened	1 (0.8%)
White blood cell count decreased	1 (0.8%)
Vascular disorders	29 (22.5%)
Phlebitis	10 (7.8%)
Flushing	9 (7.0%)
Hypotension	5 (3.9%)
Vein pain	3 (2.3%)
Deep vein thrombosis	2 (1.6%)
Essential hypertension	1 (0.8%)
Extremity necrosis	1 (0.8%)
Thrombosed varicose vein	1 (0.8%)
Vasculitis	1 (0.8%)
Venous thrombosis limb	1 (0.8%)
Nervous system disorders	24 (18.6%)
Dizziness	8 (6.2%)
Headache	6 (4.7%)

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Dysgeusia	5 (3.9%)
Ageusia	1 (0.8%)
Amnesia	1 (0.8%)
Encephalopathy	1 (0.8%)
Hypoaesthesia	1 (0.8%)
Hypotonia	1 (0.8%)
Lethargy	1 (0.8%)
Neuropathy peripheral	1 (0.8%)
Paraesthesia	1 (0.8%)
Syncope	1 (0.8%)
Skin and subcutaneous tissue disorders	22 (17.1%)
Rash	11 (8.5%)
Pruritus	5 (3.9%)
Hyperhidrosis	3 (2.3%)
Alopecia	2 (1.6%)
Dry skin	1 (0.8%)
Erythema	1 (0.8%)
Night sweats	1 (0.8%)
Palmar erythema	1 (0.8%)
Palmar-plantar erythrodysesthesia syndrome	1 (0.8%)
Rash macular	1 (0.8%)
Rash papular	1 (0.8%)
Urticaria	1 (0.8%)
Infections and infestations	19 (14.7%)
Cellulitis	3 (2.3%)
Pneumonia	3 (2.3%)
Upper respiratory tract infection	3 (2.3%)
Herpes simplex	2 (1.6%)
Infection	2 (1.6%)
Administration site infection	1 (0.8%)
Bronchitis	1 (0.8%)

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Bronchitis bacterial	1 (0.8%)
Gastroenteritis viral	1 (0.8%)
Herpes zoster	1 (0.8%)
Infusion site cellulitis	1 (0.8%)
Opportunistic infection	1 (0.8%)
Oral candidiasis	1 (0.8%)
Oral fungal infection	1 (0.8%)
Oral herpes	1 (0.8%)
Pharyngitis bacterial	1 (0.8%)
Pneumonia viral	1 (0.8%)
Sepsis	1 (0.8%)
Septic shock	1 (0.8%)
Skin candida	1 (0.8%)
Staphylococcal sepsis	1 (0.8%)
Tonsillitis	1 (0.8%)
Urinary tract infection staphylococcal	1 (0.8%)
Metabolism and nutrition disorders	18 (14.0%)
Decreased appetite	10 (7.8%)
Hypokalaemia	5 (3.9%)
Hyperglycaemia	2 (1.6%)
Tumour lysis syndrome	2 (1.6%)
Dehydration	1 (0.8%)
Hypercalcaemia	1 (0.8%)
Hyperkalaemia	1 (0.8%)
Hyperuricaemia	1 (0.8%)
Respiratory, thoracic and mediastinal disorders	16 (12.4%)
Dyspnoea	8 (6.2%)
Cough	3 (2.3%)
Hiccups	2 (1.6%)
Hypoxia	2 (1.6%)
Alveolitis	1 (0.8%)

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Bronchospasm	1 (0.8%)
Nasal congestion	1 (0.8%)
Pharyngeal ulceration	1 (0.8%)
Pulmonary embolism	1 (0.8%)
Pulmonary mass	1 (0.8%)
Rhinorrhoea	1 (0.8%)
Musculoskeletal and connective tissue disorders	12 (9.3%)
Pain in extremity	4 (3.1%)
Myalgia	3 (2.3%)
Bone pain	2 (1.6%)
Back pain	1 (0.8%)
Muscle spasms	1 (0.8%)
Musculoskeletal pain	1 (0.8%)
Injury, poisoning and procedural complications	6 (4.7%)
Infusion related reaction	5 (3.9%)
Tracheostomy malfunction	1 (0.8%)
Eye disorders	5 (3.9%)
Vision blurred	3 (2.3%)
Dry eye	1 (0.8%)
Keratoconjunctivitis sicca	1 (0.8%)
Lacrimation increased	1 (0.8%)
Toxic cataract	1 (0.8%)
Renal and urinary disorders	5 (3.9%)
Pollakiuria	2 (1.6%)
Azotaemia	1 (0.8%)
Micturition urgency	1 (0.8%)
Renal impairment	1 (0.8%)
Cardiac disorders	3 (2.3%)

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System Organ Class Preferred Term	Total (N = 129)
Atrial fibrillation	1 (0.8%)
Bundle branch block right	1 (0.8%)
Ventricular extrasystoles	1 (0.8%)
Psychiatric disorders	3 (2.3%)
Anxiety	1 (0.8%)
Confusional state	1 (0.8%)
Insomnia	1 (0.8%)
Immune system disorders	2 (1.6%)
Hypersensitivity	2 (1.6%)
Hepatobiliary disorders	1 (0.8%)
Hepatic cirrhosis	1 (0.8%)
Hepatic failure	1 (0.8%)
Reproductive system and breast disorders	1 (0.8%)
Testicular pain	1 (0.8%)