Participants With Drug-Related Adverse Events
(Incidence > 0 % in One or More Treatment Groups)
Weeks 0 to 12
All Participants as Treated

	Placebo		Low Dose		High Dose		Total	
	n	(%)	n	(%)	n	(%)	n	(%)
Participants in population	86		84		84		254	
with one or more drug-related adverse events	44	(51.2)	73	(86.9)	70	(83.3)	187	(73.6)
with no drug-related adverse events	42	(48.8)	11	(13.1)	14	(16.7)	67	(26.4)
Cardiac disorders	**6**	**(7.0)**	**7**	**(8.3)**	**4**	**(4.8)**	**17**	**(6.7)**
Atrial fibrillation	1	(1.2)	0	(0.0)	2	(2.4)	3	(1.2)
Atrial flutter	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Atrioventricular block first degree	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Atrioventricular block second degree	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Bradycardia	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Bundle branch block right	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Cardiac failure congestive	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Myocardial infarction	2	(2.3)	1	(1.2)	1	(1.2)	4	(1.6)
Palpitations	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Sinus arrhythmia	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Sinus bradycardia	2	(2.3)	2	(2.4)	0	(0.0)	4	(1.6)
Supraventricular extrasystoles	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Ventricular extrasystoles	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Wolff-parkinson-white syndrome	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Congenital, familial and genetic disorders	**0**	**(0.0)**	**1**	**(1.2)**	**0**	**(0.0)**	**1**	**(0.4)**
Ventricular septal defect	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Ear and labyrinth disorders	**0**	**(0.0)**	**2**	**(2.4)**	**1**	**(1.2)**	**3**	**(1.2)**
Tinnitus	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Vertigo	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Eye disorders	**0**	**(0.0)**	**1**	**(1.2)**	**1**	**(1.2)**	**2**	**(0.8)**
Vision blurred	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)

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Gastrointestinal disorders	**4**	**(4.7)**	**8**	**(9.5)**	**10**	**(11.9)**	**22**	**(8.7)**
Abdominal pain	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Diarrhoea	3	(3.5)	3	(3.6)	2	(2.4)	8	(3.1)
Dyspepsia	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)
Gastrooesophageal reflux disease	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Nausea	0	(0.0)	3	(3.6)	3	(3.6)	6	(2.4)
Salivary hypersecretion	0	(0.0)	0	(0.0)	3	(3.6)	3	(1.2)
Stomach discomfort	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Vomiting	0	(0.0)	2	(2.4)	3	(3.6)	5	(2.0)
General disorders and administration site conditions	**18**	**(20.9)**	**43**	**(51.2)**	**35**	**(41.7)**	**96**	**(37.8)**
Application site bleeding	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Application site dermatitis	5	(5.8)	9	(10.7)	7	(8.3)	21	(8.3)
Application site desquamation	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Application site discharge	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Application site discolouration	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Application site erythema	3	(3.5)	12	(14.3)	15	(17.9)	30	(11.8)
Application site induration	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Application site irritation	3	(3.5)	9	(10.7)	9	(10.7)	21	(8.3)
Application site pain	0	(0.0)	0	(0.0)	2	(2.4)	2	(0.8)
Application site perspiration	0	(0.0)	0	(0.0)	2	(2.4)	2	(0.8)
Application site pruritus	6	(7.0)	22	(26.2)	22	(26.2)	50	(19.7)
Application site reaction	1	(1.2)	0	(0.0)	1	(1.2)	2	(0.8)
Application site swelling	0	(0.0)	1	(1.2)	2	(2.4)	3	(1.2)
Application site urticaria	0	(0.0)	2	(2.4)	1	(1.2)	3	(1.2)
Application site vesicles	1	(1.2)	4	(4.8)	6	(7.1)	11	(4.3)
Application site warmth	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Asthenia	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Chest discomfort	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)

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Chills	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)
Fatigue	1	(1.2)	2	(2.4)	4	(4.8)	7	(2.8)
Feeling abnormal	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Malaise	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Oedema	0	(0.0)	2	(2.4)	0	(0.0)	2	(0.8)
Oedema peripheral	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Pain	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Injury, poisoning and procedural complications	**0**	**(0.0)**	**2**	**(2.4)**	**1**	**(1.2)**	**3**	**(1.2)**
Excoriation	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Fall	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Skin laceration	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Wound	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Investigations	**4**	**(4.7)**	**2**	**(2.4)**	**1**	**(1.2)**	**7**	**(2.8)**
Blood creatine phosphokinase increased	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Body temperature increased	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Electrocardiogram st segment depression	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)
Electrocardiogram t wave inversion	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Heart rate increased	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Heart rate irregular	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Metabolism and nutrition disorders	**3**	**(3.5)**	**0**	**(0.0)**	**1**	**(1.2)**	**4**	**(1.6)**
Decreased appetite	1	(1.2)	0	(0.0)	1	(1.2)	2	(0.8)
Food craving	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Increased appetite	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Musculoskeletal and connective tissue disorders	**1**	**(1.2)**	**0**	**(0.0)**	**1**	**(1.2)**	**2**	**(0.8)**
Myalgia	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Shoulder pain	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)

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Nervous system disorders	**5**	**(5.8)**	**12**	**(14.3)**	**15**	**(17.9)**	**32**	**(12.6)**
Balance disorder	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Burning sensation	0	(0.0)	0	(0.0)	2	(2.4)	2	(0.8)
Complex partial seizures	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Coordination abnormal	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Dizziness	2	(2.3)	6	(7.1)	6	(7.1)	14	(5.5)
Headache	2	(2.3)	1	(1.2)	1	(1.2)	4	(1.6)
Hypersomnia	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Lethargy	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Paraesthesia oral	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Parosmia	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Somnolence	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Stupor	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Syncope	0	(0.0)	4	(4.8)	3	(3.6)	7	(2.8)
Syncope vasovagal	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Transient ischaemic attack	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Psychiatric disorders	**2**	**(2.3)**	**9**	**(10.7)**	**5**	**(6.0)**	**16**	**(6.3)**
Agitation	0	(0.0)	2	(2.4)	0	(0.0)	2	(0.8)
Anxiety	0	(0.0)	3	(3.6)	0	(0.0)	3	(1.2)
Confusional state	1	(1.2)	2	(2.4)	0	(0.0)	3	(1.2)
Delirium	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Depressed mood	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Hallucination, visual	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Insomnia	0	(0.0)	0	(0.0)	2	(2.4)	2	(0.8)
Irritability	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)
Libido decreased	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Listless	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Restlessness	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Renal and urinary disorders	**0**	**(0.0)**	**1**	**(1.2)**	**1**	**(1.2)**	**2**	**(0.8)**
Enuresis	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Micturition urgency	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Reproductive system and breast disorders	**1**	**(1.2)**	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(0.4)**

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	n	(%)	n	(%)	n	(%)	n	(%)
Pelvic pain	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Respiratory, thoracic and mediastinal disorders	**2**	**(2.3)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(0.8)**
Dyspnoea	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Emphysema	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Skin and subcutaneous tissue disorders	**17**	**(19.8)**	**39**	**(46.4)**	**39**	**(46.4)**	**95**	**(37.4)**
Blister	0	(0.0)	5	(6.0)	1	(1.2)	6	(2.4)
Cold sweat	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Dermatitis contact	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Erythema	9	(10.5)	13	(15.5)	14	(16.7)	36	(14.2)
Hyperhidrosis	1	(1.2)	4	(4.8)	8	(9.5)	13	(5.1)
Pruritus	7	(8.1)	21	(25.0)	26	(31.0)	54	(21.3)
Pruritus generalised	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Rash	3	(3.5)	11	(13.1)	7	(8.3)	21	(8.3)
Rash erythematous	0	(0.0)	2	(2.4)	0	(0.0)	2	(0.8)
Rash maculo-papular	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Rash papular	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)
Rash pruritic	0	(0.0)	1	(1.2)	2	(2.4)	3	(1.2)
Skin exfoliation	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Skin irritation	2	(2.3)	6	(7.1)	5	(6.0)	13	(5.1)
Skin ulcer	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Urticaria	0	(0.0)	1	(1.2)	1	(1.2)	2	(0.8)
Vascular disorders	**1**	**(1.2)**	**2**	**(2.4)**	**1**	**(1.2)**	**4**	**(1.6)**
Hypertension	0	(0.0)	1	(1.2)	0	(0.0)	1	(0.4)
Hypotension	1	(1.2)	1	(1.2)	0	(0.0)	2	(0.8)
Orthostatic hypotension	1	(1.2)	0	(0.0)	0	(0.0)	1	(0.4)
Wound haemorrhage	0	(0.0)	0	(0.0)	1	(1.2)	1	(0.4)

Every participant is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
Adverse event terms are from MedDRA Version 24.0.

Source: [CDISCpilot: adam-adsl; adae]