

Table 2. Incidences of adverse drug reactions (safety analysis set)

	Adults (n=267)	%	Children (n=98)	%	Overall (n=365)	%
Adverse drug reactions ^{a, b)}	45	16.85	20	20.41	65	17.81
Decreased appetite	1	0.37	1	1.02	2	0.55
Aggression	1	0.37	1	1.02	2	0.55
Agitation	1	0.37	5	5.10	6	1.64
Insomnia	1	0.37	1	1.02	2	0.55
Irritability	5	1.87	2	2.04	7	1.92
Dizziness	3	1.12	1	1.02	4	1.10
Epilepsy ^{c)}	2	0.75	0	0.00	2	0.55
Headaches	0	0.00	3	3.06	3	0.82
Somnolence	19	7.12	6	6.12	25	6.85
Alanine aminotransferase increased	2	0.75	0	0.00	2	0.55
Aspartate aminotransferase increased	2	0.75	1	1.02	3	0.82
Blood lactate dehydrogenase increased	1	0.37	1	1.02	2	0.55
Gamma-glutamyltransferase increased	3	1.12	0	0.00	3	0.82

a) MedDRA/J version 22.1, Preferred term

b) Lists the ADRs which occurred in more than or equal to 2 patients in total

c) Epilepsy: seizure aggravation and/or increase in seizure frequency were reported