

Table S2 Onset of adverse drug reactions (in 2% or more of patients, by SOC); safety analysis set

Safety analysis set	989
No. of patients with ADRs	237
No. of ADRs	354
Incidence of ADRs	24.0%
Type of ADR ^a	No. of patients (%)
Psychiatric disorders	36 (3.6)
Aggression	2 (0.2)
Agitation	1 (0.1)
Anger	5 (0.5)
Anxiety	3 (0.3)
Depersonalization	1 (0.1)
Depression	1 (0.1)
Dissociative disorder	1 (0.1)
Hypomania	2 (0.2)
Insomnia	4 (0.4)
Intentional self-injury	1 (0.1)
Irritability	10 (1.0)
Mania	3 (0.3)
Panic attack	1 (0.1)
Suicidal ideation	4 (0.4)
Depressive symptom	2 (0.2)
BD	1 (0.1)
Abnormal behavior	1 (0.1)
Somatic hallucination	1 (0.1)
Nervous system disorders	37 (3.7)
Akathisia	1 (0.1)
Disturbance in attention	2 (0.2)
Dizziness	7 (0.7)
Dizziness postural	1 (0.1)
Dysarthria	1 (0.1)
Headache	7 (0.7)
Hypersomnia	3 (0.3)
Hypoesthesia	1 (0.1)
Migraine	1 (0.1)
Neuralgia	1 (0.1)
Paresthesia	1 (0.1)
Sedation	1 (0.1)

Somnolence	13 (1.3)
Tremor	5 (0.5)
Cognitive disorder	1 (0.1)
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Gastrointestinal disorders	23 (2.3)
Abdominal discomfort	2 (0.2)
Abdominal distension	1 (0.1)
Abdominal pain upper	1 (0.1)
Aphthous ulcer	1 (0.1)
Constipation	3 (0.3)
Diarrhea	2 (0.2)
Eructation	1 (0.1)
Glossitis	1 (0.1)
Glossodynia	2 (0.2)
Nausea	4 (0.4)
Oral pain	1 (0.1)
Stomatitis	5 (0.5)
Vomiting	1 (0.1)
Lip erosion	1 (0.1)
Hypoesthesia oral	2 (0.2)
Lip exfoliation	1 (0.1)
Mouth swelling	1 (0.1)
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Skin and subcutaneous tissue disorders	130 (13.1)
Blister	1 (0.1)
Chloasma	1 (0.1)
Cold sweat	1 (0.1)
Drug eruption	10 (1.0)
Eczema	5 (0.5)
Erythema	9 (0.9)
Erythema multiforme	2 (0.2)
Pruritus	12 (1.2)
Purpura	1 (0.1)
Rash	90 (9.1)
Rash macular	1 (0.1)
Rash maculo-papular	2 (0.2)
Skin disorder	1 (0.1)
Skin erosion	1 (0.1)
Skin exfoliation	1 (0.1)
Stevens–Johnson syndrome	2 (0.2)

Swelling face	1 (0.1)
Generalized erythema	1 (0.1)
Toxic skin eruption	1 (0.1)
Drug reaction with eosinophilia and systemic symptoms	3 (0.3)

Note: ^aMedDRA/J version 18.1 codes.

Abbreviations: ADR, adverse drug reaction; BD, bipolar disorder.