

**Table 2. Summary of safety and tolerability**

<b>Total patients</b>	<b>N=3006</b>
Patients with any AE, n (%)	1664 (55.4)
Most frequently reported AEs <sup>a</sup> , n (%)	
Dizziness/vertigo	515 (17.1)
Behavioral (aggression/anger/irritability)	491 (16.3)
Somnolence	371 (12.3)
Fatigue	150 (5.0)
Patients with AEs leading to discontinuation, n (%)	460 (14.4) <sup>b</sup>
Patients with any psychiatric AE, n (%)	675 (22.5)
Patients with psychiatric AEs leading to discontinuation, n (%)	273 (9.1)
Most frequently reported psychiatric AEs leading to discontinuation <sup>c</sup> , n (%)	
Behavioral (aggression/anger/irritability)	187 (6.2)
Depressed mood/mood disturbance	52 (1.7)
<sup>a</sup> ≥5% patients; <sup>b</sup> N=3188; <sup>c</sup> ≥1% patients. AE, adverse event.	