

Table 1.
Incidence of TEAE at least possibly related (>2,5%) in patients taking ESL and one AED (any)

Dictionary-Derived Term	Actual Treatment Group									
	ESL Total		ESL 1200 mg		ESL 800 mg		ESL 400 mg		Placebo	
TEAE, n (%)	328		131		136		61		127	
Dizziness	50	15.2	23	17.6	23	16.9	4	6.6	7	5.5
Somnolence	39	11.9	22	16.8	11	8.1	6	9.8	9	7.1
Nausea	25	7.6	14	10.7	9	6.6	2	3.3	2	1.6
Vomiting	15	4.6	11	8.4	4	2.9	0	0	0	0
Headache	21	6.4	10	7.6	9	6.6	2	3.3	5	3.9
Diplopia	17	5.2	9	6.9	7	5.1	1	1.6	0	0
Vertigo	12	3.7	6	4.6	4	2.9	2	3.3	0	0
Tremor	7	2.1	6	4.6	1	0.7	0	0	0	0
Fatigue	10	3.0	4	3.1	5	3.7	1	1.6	3	2.4
Ataxia	6	1.8	4	3.1	1	0.7	1	1.6	0	0
Vision blurred	6	1.8	4	3.1	0	0	2	3.3	2	1.6
Insomnia	3	0.9	1	0.8	0	0	2	3.3	0	0
Weight increased	3	0.9	1	0.8	0	0	2	3.3	2	1.6
Seizure	3	0.9	0	0	1	0.7	2	3.3	1	0.8
Blood pressure systolic decreased	2	0.6	0	0	0	0	2	3.3	0	0

Incidence of discontinuation due to TEAE (>1% in any arm) in patients taking one AED (any)

Dictionary-Derived Term	Actual Treatment Group									
	ESL Total		ESL 1200 mg		ESL 800 mg		ESL 400 mg		Placebo	
	328		131		136		61		127	
Dizziness	16	4.9	10	7.6	6	4.4	0	0	0	0
Somnolence	7	2.1	7	5.3	0	0	0	0	2	1.6
Nausea	8	2.4	7	5.3	1	0.7	0	0	0	0
Vomiting	8	2.4	7	5.3	1	0.7	0	0	0	0
Diplopia	6	1.8	3	2.3	3	2.2	0	0	0	0
Ataxia	3	0.9	3	2.3	0	0	0	0	0	0
Vision blurred	3	0.9	3	2.3	0	0	0	0	0	0
Asthenia	3	0.9	3	2.3	0	0	0	0	0	0
Vertigo	3	0.9	2	1.5	1	0.7	0	0	0	0
Fatigue	2	0.6	2	1.5	0	0	0	0	0	0
Depression	3	0.9	2	1.5	0	0	1	1.6	0	0
Insomnia	2	0.6	2	1.5	0	0	0	0	0	0
Coordination abnormal	2	0.6	2	1.5	0	0	0	0	0	0
Irritability	3	0.9	2	1.5	1	0.7	0	0	0	0
Nervousness	2	0.6	2	1.5	0	0	0	0	0	0

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Partial seizures	0	0	0	0	0	0	0	0	0	4	3.1
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AED, antiepileptic drug; ESL, Eslicarbazepine acetate, TEAE, Treatment Emergent Adverse Events

