

Safety, Tolerability and Efficacy of Eslicarbazepine Acetate as Adjunctive Therapy in Patients Aged ≥65 Years with Focal Seizures

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Table 1. Summary of TEAEs by Gender ($\geq 5\%$ in any gender group, safety population N=72)

	Female (N = 34) n (%) ne	Male (N = 38) n (%) ne
Patients with at least one TEAE	21 (61.8%) 77	26 (68.4%) 75
Dizziness	5 (14.7%) 7	4 (10.5%) 4
Somnolence	4 (11.8%) 4	3 (7.9%) 3
Convulsion	5 (14.7%) 5	1 (2.6%) 1
Fatigue	2 (5.9%) 2	4 (10.5%) 5
Hyponatraemia	3 (8.8%) 3	3 (7.9%) 3
Nasopharyngitis	3 (8.8%) 3	2 (5.3%) 2
Upper respiratory tract infection	4 (11.8%) 5	—
Bronchitis	1 (2.9%) 1	2 (5.3%) 2
Blood creatine phosphokinase increased	2 (5.9%) 2	1 (2.6%) 1
Gamma-glutamyltransferase increased	2 (5.9%) 2	1 (2.6%) 1
Back pain	2 (5.9%) 2	—
Headache	—	2 (5.3%) 5
Hypertension	2 (5.9%) 2	—
Constipation	—	2 (5.3%) 2

N = Number of patients in Safety Set; n = Number of patients having the event; %, proportion of patients having the event; ne = Number of TEAEs.

Table 2. Summary of TEAEs by Age Group (> 1 subject in any age group, safety population N=72)

	65-69 years (N = 30) n (%) ne	70-74 years (N = 19) n (%) ne	75-79 years (N = 19) n (%) ne	80-84 years (N = 4) n (%) ne
Patients with at least one TEAE	20 (66.7%) 48	12 (63.2%) 59	13 (68.4%) 41	2 (50.0%) 4
Dizziness	4 (13.3%) 4	3 (15.8%) 4	2 (10.5%) 3	—
Somnolence	4 (13.3%) 4	1 (5.3%) 1	2 (10.5%) 2	—
Fatigue	1 (3.3%) 1	4 (21.1%) 5	1 (5.3%) 1	—
Hyponatraemia	3 (10.0%) 3	3 (15.8%) 3	—	—
Convulsion	—	4 (21.1%) 4	1 (5.3%) 1	1 (25.0%) 1
Nasopharyngitis	3 (10.0%) 3	2 (10.5%) 2	—	—
Upper respiratory tract infection	3 (10.0%) 3	1 (5.3%) 2	—	—
Blood creatine phosphokinase increased	2 (6.7%) 2	1 (5.3%) 1	—	—
Gamma-glutamyltransferase increased	—	2 (10.5%) 2	1 (5.3%) 1	—
Bronchitis	3 (10.0%) 3	—	—	—
Back pain	—	—	2 (10.5%) 2	—
Rash	2 (6.7%) 2	—	—	—

N = Number of patients in Safety Set; n = Number of patients having the event; %, proportion of patients having the event; ne = Number of TEAEs.

Table 3: Summary of Scales for Evaluation of Sedative Effects (safety population N=72)

Scale	Visit	Statistic	Absolute value	Absolute change	Relative change (%)	
How much alert do you feel? (0=drowsy, 10=alert)	V2	n	71			
		Mean (SD)	6.9 (2.31)			
		Median	7.0			
	V5	n	55		54	54
		Mean (SD)	6.8 (2.06)	-0.3 (1.82)		-0.5 (25.59)
		Median	7.0	0.0		0.0
	V6/EDV	n	65		64	63
		Mean (SD)	6.2 (2.40)	-0.8 (2.68)		-6.7 (35.18)
		Median	6.0	0.0		0.0
How much clear-headed do you feel? (0=muzzy, 10=clear-headed)	V2	n	71			
		Mean (SD)	6.6 (2.52)			
		Median	7.0			
	V5	n	55		54	54
		Mean (SD)	7.0 (2.06)	0.1 (1.98)		6.5 (36.90)
		Median	7.0	0.0		0.0
	V6/EDV	n	65		64	62
		Mean (SD)	6.4 (2.26)	-0.3 (2.04)		4.1 (52.24)
		Median	7.0	0.0		0.0
How much quick-witted do you feel? (0=mentally slow, 10=quick-witted)	V2	n	71			
		Mean (SD)	6.8 (2.30)			
		Median	7.0			
	V5	n	55		54	54
		Mean (SD)	6.5 (2.39)	-0.4 (2.03)		-1.1 (34.32)
		Median	6.0	0.0		0.0
	V6/EDV	n	65		64	64
		Mean (SD)	6.3 (2.33)	-0.6 (2.42)		1.8 (62.46)
		Median	6.0	0.0		0.0
How much attentive do you feel? (0=dreamy, 10=attentive)	V2	n	71			
		Mean (SD)	7.0 (2.33)			
		Median	7.0			
	V5	n	55		54	54
		Mean (SD)	6.9 (2.16)	-0.4 (1.56)		-3.5 (23.86)
		Median	7.0	0.0		0.0
	V6/EDV	n	65		64	62
		Mean (SD)	6.7 (2.35)	-0.4 (1.97)		-3.9 (30.15)
		Median	7.0	0.0		0.0
		Min/Max	0.0/10.0	-6.0/4.0	-80.0/100.0	

V, visit; EDV, Early Discontinuation Visit; SD: Standard deviation.

Table 4: Overview of Patient's Global Impression of Change of Intellectual Ability

PGIC	Full Analysis Set (N=71) n (%)	Per Protocol Set (N=55) n (%)
Very much improved	7 (9.9%)	5 (9.1%)
Much improved	22 (31.0%)	20 (36.4%)
Minimally improved	4 (5.6%)	4 (7.3%)
No change	19 (26.8%)	13 (23.6%)
Minimally worse	8 (11.3%)	6 (10.9%)
Much worse	4 (5.6%)	4 (7.3%)
Very much worse	—	—
Missing	7 (9.9%)	3 (5.5%)

PGIC, Patient Global Impression of Change; N: Number of patients in specified set; n: Number of patients within each category; %: Percentage based on N.