

Rapid Onset of Crisugabalin in Patients with Diabetic Peripheral Neuropathic Pain: Findings from a Multicenter, Randomized, Double-Blind Controlled Study

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Supplementary Table 1. Weekly ADPS Change from Baseline: FAS (Imputed)

Week	Crisugabalin 40 mg/d (N=178)	Crisugabalin 80 mg/d (N=179)	Placebo (N=177)	Pregabalin (N=62)
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD
1	-0.36 $\pm$ 0.71**	-0.35 $\pm$ 0.72**	-0.11 $\pm$ 0.53	-0.16 $\pm$ 0.56
2	-0.68 $\pm$ 0.99**	-0.74 $\pm$ 1.07**	-0.38 $\pm$ 0.84	-0.59 $\pm$ 0.80
3	-0.81 $\pm$ 1.10*	-0.79 $\pm$ 1.19*	-0.53 $\pm$ 1.00	-0.71 $\pm$ 0.93
4	-1.00 $\pm$ 1.09**	-1.06 $\pm$ 1.25**	-0.68 $\pm$ 1.08	-0.93 $\pm$ 1.07
5	-1.09 $\pm$ 1.17**	-1.10 $\pm$ 1.30**	-0.75 $\pm$ 1.14	-0.99 $\pm$ 1.10
6	-1.19 $\pm$ 1.20*	-1.22 $\pm$ 1.36*	-0.89 $\pm$ 1.24	-1.17 $\pm$ 1.26
7	-1.21 $\pm$ 1.29*	-1.30 $\pm$ 1.44**	-0.92 $\pm$ 1.28	-1.30 $\pm$ 1.32
8	-1.35 $\pm$ 1.34*	-1.44 $\pm$ 1.46**	-0.98 $\pm$ 1.37	-1.38 $\pm$ 1.30
9	-1.42 $\pm$ 1.37*	-1.51 $\pm$ 1.50**	-1.04 $\pm$ 1.43	-1.42 $\pm$ 1.30
10	-1.55 $\pm$ 1.41**	-1.59 $\pm$ 1.55**	-1.10 $\pm$ 1.53	-1.57 $\pm$ 1.42*
11	-1.59 $\pm$ 1.44**	-1.69 $\pm$ 1.56**	-1.13 $\pm$ 1.64	-1.60 $\pm$ 1.43*
12	-1.88 $\pm$ 1.53**	-1.96 $\pm$ 1.71**	-1.19 $\pm$ 1.67	-1.76 $\pm$ 1.53*
13	-2.03 $\pm$ 1.59**	-2.06 $\pm$ 1.78**	-1.23 $\pm$ 1.69	-1.87 $\pm$ 1.62*

Abbreviation: ADPS: average daily pain score; FAS: Full Analysis Set; SD: Standard Deviation.

Least-Significant Difference (LSD) method; * $P < 0.05$, ** $P < 0.01$ vs. Placebo.

Supplementary Table 2. Day 14 NRS Score Change from Baseline: FAS (Imputed)

Day	Crisugabalin 40 mg/d (N=178)	Crisugabalin 80 mg/d (N=179)	Placebo (N=177)	Pregabalin (N=62)
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD
1	0.00 $\pm$ 0.94	0.02 $\pm$ 1.01	-0.03 $\pm$ 0.53	0.05 $\pm$ 0.61
2	-0.24 $\pm$ 0.69*	-0.18 $\pm$ 0.71	-0.08 $\pm$ 0.64	-0.14 $\pm$ 0.62
3	-0.30 $\pm$ 0.81*	-0.36 $\pm$ 0.94**	-0.11 $\pm$ 0.64	-0.20 $\pm$ 0.65
4	-0.42 $\pm$ 0.94**	-0.38 $\pm$ 0.84**	-0.12 $\pm$ 0.69	-0.17 $\pm$ 0.80
5	-0.49 $\pm$ 0.94**	-0.48 $\pm$ 1.05**	-0.11 $\pm$ 0.71	-0.14 $\pm$ 0.77
6	-0.51 $\pm$ 0.94**	-0.47 $\pm$ 0.97**	-0.17 $\pm$ 0.77	-0.27 $\pm$ 0.64
7	-0.51 $\pm$ 1.01**	-0.59 $\pm$ 1.09**	-0.23 $\pm$ 0.78	-0.27 $\pm$ 0.71
8	-0.61 $\pm$ 1.02**	-0.72 $\pm$ 1.15**	-0.32 $\pm$ 0.82	-0.45 $\pm$ 0.72
9	-0.67 $\pm$ 1.01**	-0.69 $\pm$ 1.14**	-0.30 $\pm$ 0.83	-0.48 $\pm$ 0.76
10	-0.64 $\pm$ 1.11*	-0.72 $\pm$ 1.15**	-0.38 $\pm$ 0.85	-0.59 $\pm$ 0.88
11	-0.65 $\pm$ 1.03	-0.74 $\pm$ 1.14**	-0.45 $\pm$ 1.03	-0.62 $\pm$ 0.92
12	-0.65 $\pm$ 1.09*	-0.78 $\pm$ 1.19**	-0.42 $\pm$ 1.02	-0.65 $\pm$ 0.92
13	-0.76 $\pm$ 1.12**	-0.77 $\pm$ 1.13**	-0.44 $\pm$ 1.02	-0.67 $\pm$ 0.94
14	-0.78 $\pm$ 1.17**	-0.78 $\pm$ 1.18**	-0.47 $\pm$ 1.03	-0.63 $\pm$ 0.96

Abbreviation: NRS: Numeric Rating Scale; FAS: Full Analysis Set; SD: Standard Deviation.

Least-Significant Difference (LSD) method; * $P < 0.05$, ** $P < 0.01$ vs. Placebo.

Supplementary Table 3. Day 14 DSIS Change from Baseline: FAS (Imputed)

Day	Crisugabalin 40 mg/d (N=178)	Crisugabalin 80 mg/d (N=179)	Placebo (N=177)	Pregabalin (N=62)
	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD	Mean $\pm$ SD
1	0.03 $\pm$ 0.90	0.04 $\pm$ 1.07	0.03 $\pm$ 0.65	-0.10 $\pm$ 0.87
2	-0.14 $\pm$ 0.96	-0.23 $\pm$ 0.79**	0.02 $\pm$ 0.74	-0.12 $\pm$ 0.81
3	-0.21 $\pm$ 0.88**	-0.37 $\pm$ 0.95**	0.06 $\pm$ 0.78	-0.18 $\pm$ 0.79
4	-0.24 $\pm$ 0.82*	-0.37 $\pm$ 0.93**	-0.01 $\pm$ 0.77	-0.21 $\pm$ 0.87
5	-0.36 $\pm$ 0.94**	-0.38 $\pm$ 0.96**	0.03 $\pm$ 0.82	-0.26 $\pm$ 0.91*
6	-0.34 $\pm$ 0.92**	-0.43 $\pm$ 1.01**	-0.01 $\pm$ 0.84	-0.21 $\pm$ 1.18
7	-0.34 $\pm$ 0.94*	-0.54 $\pm$ 1.08**	-0.11 $\pm$ 0.87	-0.24 $\pm$ 0.64
8	-0.46 $\pm$ 1.02*	-0.65 $\pm$ 1.10**	-0.21 $\pm$ 0.91	-0.36 $\pm$ 0.68
9	-0.45 $\pm$ 0.99*	-0.61 $\pm$ 1.09**	-0.19 $\pm$ 0.92	-0.33 $\pm$ 0.80
10	-0.47 $\pm$ 0.99*	-0.68 $\pm$ 1.13**	-0.23 $\pm$ 1.02	-0.37 $\pm$ 1.11
11	-0.44 $\pm$ 0.96	-0.69 $\pm$ 1.12**	-0.23 $\pm$ 1.09	-0.49 $\pm$ 0.85
12	-0.48 $\pm$ 1.00	-0.71 $\pm$ 1.15**	-0.26 $\pm$ 1.09	-0.47 $\pm$ 0.93
13	-0.51 $\pm$ 0.98*	-0.72 $\pm$ 1.15**	-0.25 $\pm$ 1.10	-0.45 $\pm$ 1.02
14	-0.52 $\pm$ 1.05*	-0.70 $\pm$ 1.15**	-0.29 $\pm$ 1.05	-0.53 $\pm$ 1.12

Abbreviation: DSIS: daily sleep interference score; FAS: Full Analysis Set; SD: Standard Deviation.

Least-Significant Difference (LSD) method; * $P < 0.05$, ** $P < 0.01$ vs. Placebo.