Supplementary Online Content

Bogan RK, Cramer Bornemann MA, Kushida CA, Trân PV, Barrett RW; XP060 Study Group. Long-term maintenance treatment of restless legs syndrome with gabapentin enacarbil: a randomized controlled study. *Mayo Clin Proc*. 2010;85(6):512-521.

eTABLE 1. Post-Sleep Questionnaire Responses at Single-Blind and Double-Blind Baselines for the Intent-to-Treat Populations

eTABLE 2. Treatment-Emergent Adverse Events Occurring During the 2-Week Taper Phase Between Weeks 24 and 26 in the Double-Blind Safety Population

This supplementary material has been peer reviewed, edited, and approved by the authors.

©2010 Mayo Foundation for Medical Education and Research. All rights reserved.

eTABLE 1. **Post-Sleep Questionnaire Responses at Single-Blind and Double-Blind Baselines for the Intent-to-Treat Populations**[a]

	No. (%) of patients		
	Single-blind phase of gabapentin enacarbil, 1200 mg (n=311)	Double-blind phase	
		Placebo (n=97)	Gabapentin enacarbil, 1200 mg (n=96)
Item 1: overall quality of sleep in past week			
Excellent	3 (1.0)	38 (39)	43 (45)
Reasonable	97 (31.2)	56 (58)	46 (48)
Poor	211 (67.8)	3 (3)	7 (7)
Item 2: ability to function in past week			
Excellent	20 (6.4)	53 (55)	63 (66)
Good	124 (39.9)	42 (43)	28 (29)
Moderate	141 (45.3)	2 (2)	4 (4)
Poor	26 (8.4)	0	1 (1)
Item 3: No. of nights with RLS symptoms in past week			
0[b]	1 (0.3)	47 (48)	38 (40)
1-2	1 (0.3)	35 (36)	36 (38)
3-4	36 (11.6)	8 (8)	11 (11)
5-6	122 (39.2)	3 (3)	5 (5)
7	151 (48.6)	4 (4)	6 (6)
Item 4: No. of awakenings during night in past week due to RLS symptoms			
0[b]	26 (8.4)	73 (75)	72 (75)
1-2	131 (42.1)	22 (23)	22 (23)
3-4	113 (36.3)	2 (2)	1 (1)
≥5	41 (13.2)	0	1 (1)
Item 5: No. of hours awake per night in past week due to RLS symptoms			
0[b]	1 (0.3)	47 (48)	38 (40)
<1	89 (28.6)	38 (39)	48 (50)
1 to <2	114 (36.7)	8 (8)	6 (6)
2 to <3	66 (21.2)	2 (2)	4 (4)
≥3	41 (13.2)	2 (2)	0

[a] RLS = restless legs syndrome.
[b] If a patient answered 0 to item 3, then his/her answers to items 4 and 5 were 0 times and 0 hours, respectively.

eTABLE 2. **Treatment-Emergent Adverse Events Occurring During the 2-Week Taper Phase Between Weeks 24 and 26 in the Double-Blind Safety Population**[a]

Adverse event	Placebo[b] (n=98)	Gabapentin enacarbil, 1200 mg (n=96)
Any	28 (29)	18 (19)
Tremor	3 (3)	2 (2)
Anxiety	1 (1)	1 (1)
Arthralgia	0	1 (1)
Cough	0	1 (1)
Diarrhea	0	1 (1)
Headache	2 (2)	1 (1)
Incontinence	0	1 (1)
Increased blood creatine kinase	0	1 (1)
Increased lacrimation	0	1 (1)
Increased mean cell volume	0	1 (1)
Increased monocyte count	0	1 (1)
Middle-of-the-night insomnia	0	1 (1)
Nasopharyngitis	0	1 (1)
Nausea	1 (1)	1 (1)
Nystagmus	1 (1)	1 (1)
Positive urine leukocyte esterase	0	1 (1)
Postnasal drip	0	1 (1)
Sleep terror	0	1 (1)
Thirst	0	1 (1)
Upper respiratory tract infection	1 (1)	1 (1)
Urinary tract infection	0	1 (1)
Insomnia	2 (2)	0
Rash	2 (2)	0
Sinusitis	2 (2)	0
Viral gastroenteritis	2 (2)	0
Acute sinusitis	1 (1)	0
Right bundle branch block	1 (1)	0
Constipation	1 (1)	0
Depression	1 (1)	0
Feeling hot and cold	1 (1)	0
Glossitis	1 (1)	0
Hemoglobinuria	1 (1)	0
Migraine	1 (1)	0
Muscle spasms	1 (1)	0
Paraesthesia	1 (1)	0
Restless legs syndrome	1 (1)	0
Ruptured tendon	1 (1)	0
Sunburn	1 (1)	0
Tarsal tunnel syndrome	1 (1)	0
Tendonitis	1 (1)	0

[a] Data are number (percentage) of adverse events.
[b] Patients in the placebo group received gabapentin enacarbil, 600 mg, during the 2-week taper phase.