

Regulatory Response

LV248886

Table 4.20. Treatment-Emergent Adverse Events Collected by AMDP-5 By Decreasing Frequency All Patients who Entered Study Period IV F1J-MC-HMCQ Study Period IV

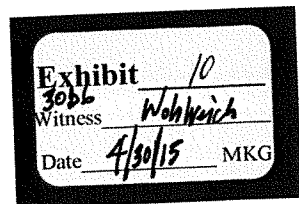
	DULOX N=81 n (%)	VENLAFAX N=202 n (%)	Total N=283 n (%)	P-Value* Overall
----- PATIENTS WITH >= 1 TESS -----				
Dizziness	60 (74.1)	164 (81.2)	224 (79.2)	.197
Increased dreams/nightmares	24 (29.6)	69 (34.2)	93 (32.9)	.487
Nausea	19 (23.5)	32 (15.8)	51 (18.0)	.170
Excessive appetite	6 (7.4)	35 (17.3)	41 (14.5)	.039
Blurred vision	10 (12.3)	27 (13.4)	37 (13.1)	1.00
Diarrhea	10 (12.3)	25 (12.4)	35 (12.4)	1.00
Headache	3 (3.7)	28 (13.9)	31 (11.0)	.011
Difficulty falling asleep	5 (6.2)	25 (12.4)	30 (10.6)	.140
Drowsiness	5 (6.2)	24 (11.9)	29 (10.2)	.195
Hot flashes	7 (8.6)	22 (10.9)	29 (10.2)	.668
Gastric discomfort	6 (7.4)	22 (10.9)	28 (9.9)	.509
Vomiting	2 (2.5)	23 (11.4)	25 (8.8)	.019
Chills	3 (3.7)	21 (10.4)	24 (8.5)	.096
Early waking	7 (8.6)	17 (8.4)	24 (8.5)	1.00
Increased perspiration	4 (4.9)	20 (9.9)	24 (8.5)	.239
Shortened sleep	7 (8.6)	15 (7.4)	22 (7.8)	.806
Excessive thirst	2 (2.5)	19 (9.4)	21 (7.4)	.046
Somatic anxiety	4 (4.9)	15 (7.4)	19 (6.7)	.602
Tremor	7 (8.6)	11 (5.4)	18 (6.4)	.418
Palpitations	4 (4.9)	13 (6.4)	17 (6.0)	.786
Paresthesia	5 (6.2)	13 (6.4)	17 (6.0)	1.00
Breathing difficulties	3 (3.7)	13 (6.4)	16 (5.7)	.570
Hypertonia	2 (2.5)	14 (6.9)	16 (5.7)	.167
Constipation	4 (4.9)	11 (5.4)	15 (5.3)	1.00

*P-Value is from Fisher's Exact test.
Program: RMP.F1JSMCQ.SASPGM(FQAES51C) QCA700
Data: RMP.SAS.F1J.M.L.MCHMCQSW.FINAL

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Regulatory Response

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Treatment-Emergent Adverse Events Collected by AMDP-5
 By Decreasing Frequency
 All Patients who Entered Study Period IV
 FLU-MC-HMCQ Study Period IV

	DULOX N=81 n(%)	VENLAFAX N=202 n(%)	Total N=283 n(%)	P-Value* Overall
0 Decreased appetite	2 (2.5)	13 (6.4)	15 (5.3)	.246
Heaviness in the legs	4 (4.9)	11 (5.4)	15 (5.3)	1.00
Interrupted sleep	3 (3.7)	12 (5.9)	15 (5.3)	.567
Backache	2 (2.5)	10 (5.0)	12 (4.2)	.519
Dry mouth	3 (3.7)	8 (4.0)	11 (3.9)	1.00
Ataxia	5 (6.2)	4 (2.0)	9 (3.2)	.125
Decreased libido	3 (3.7)	6 (3.0)	9 (3.2)	.719
Micturition difficulties	1 (1.2)	6 (3.0)	7 (2.5)	.677
Dependent edema	1 (1.2)	6 (3.0)	7 (2.5)	.677
Increased blood pressure	1 (1.2)	5 (2.5)	6 (2.1)	.187
Akathisia	0 (0.0)	6 (3.0)	6 (2.1)	1.00
Hypersalivation	2 (2.5)	4 (2.0)	6 (2.1)	
Seborrhea	1 (1.2)	3 (1.5)	4 (1.4)	
Cardiac pain	1 (1.2)	3 (1.5)	4 (1.4)	
Nyctagmus	0 (0.0)	3 (1.5)	3 (1.1)	
Acute dyskinesia	2 (2.5)	1 (0.5)	3 (1.1)	
Menstrual difficulties	1 (1.2)	1 (0.5)	2 (0.7)	
Allergic reactions	0 (0.0)	2 (1.0)	2 (0.7)	
Hypokinesia	1 (1.2)	1 (0.5)	2 (0.7)	
Increased hypertension	0 (0.0)	1 (0.5)	1 (0.4)	
Conversion symptoms	0 (0.0)	1 (0.5)	1 (0.4)	
Hypotonia	1 (1.2)	0 (0.0)	1 (0.4)	

*p-Value is from Fisher's Exact Test.
 Program: RMP.PL05EMCO.SASPGM(FOASSIC) QCA700
 Data: RMP.SAS.PL05MCO.SASPGM.FINAL

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