

CONFIDENTIAL

LY248686

Regulatory Response

Table 4.35. Treatment-Emergent Adverse Events Collected by AMDP-5
By Decreasing Frequency
All Patients who Entered Study Period IV
F1J-MC-HMBU Study Period IV

	DULOX N=114 n(%)	VENLAFAX N=126 n(%)	Total N=240 n(%)	p-Value* Overall

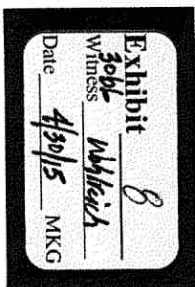
OPATIENTS WITH >= 1 TEAE	89(78.1)	85(67.5)	174(72.5)	.082
Dizziness	21(18.4)	29(23.0)	50(20.8)	.428
Blurred vision	16(14.0)	19(15.1)	35(14.6)	.856
Increased dreams/nightmares	10(8.8)	24(19.0)	34(14.2)	.026
Difficulty falling asleep	12(10.5)	14(11.1)	26(10.8)	1.00
Nausea	11(9.6)	14(11.1)	25(10.4)	.833
Diarrhea	17(14.9)	7(5.6)	24(10.0)	.018
Palpitations	5(4.4)	17(13.5)	22(9.2)	.023
Vomiting	9(7.9)	10(7.9)	19(7.9)	1.00
Backache	9(7.9)	9(7.1)	18(7.5)	1.00
Somatic anxiety	10(8.8)	8(6.3)	18(7.5)	.625
Excessive appetite	7(6.1)	10(7.9)	17(7.1)	.624
Hot flashes	8(7.0)	9(7.1)	17(7.1)	1.00
Shortened sleep	8(7.0)	9(7.1)	17(7.1)	1.00
Paresthesia	8(7.0)	8(6.3)	16(6.7)	1.00
Increased perspiration	6(5.3)	8(6.3)	14(5.8)	.788
Headache	6(5.3)	7(5.6)	13(5.4)	1.00
Interrupted sleep	5(4.4)	8(6.3)	13(5.4)	.577
Tremor	6(5.3)	7(5.6)	13(5.4)	1.00
Cardiac pain	5(4.4)	7(5.6)	12(5.0)	.772
Decreased libido	6(5.3)	6(4.8)	12(5.0)	1.00
Gastric discomfort	6(5.3)	6(4.8)	12(5.0)	1.00
Hypertonia	8(7.0)	4(3.2)	12(5.0)	.238
Chills	4(3.5)	7(5.6)	11(4.6)	.545
Drowsiness	4(3.5)	7(5.6)	11(4.6)	.545

0*p-Value is from Fisher's Exact test.
Program: RMP.F1JSHMBU.SASPGM(FQA8891C) QCA700
Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL

1PRODUCTION DATA - PRODUCTION MODE

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

CYM-00145306



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Regulatory Response

	DULOX N=114 n(%)	VENLAFAX N=126 n(%)	Total N=240 n(%)	p-Value* Overall
0 Breathing difficulties	3 (2.6)	7 (5.6)	10 (4.2)	.340
Early waking	3 (2.6)	7 (5.6)	10 (4.2)	.340
Excessive thirst	6 (5.3)	4 (3.2)	10 (4.2)	.524
Constipation	4 (3.5)	5 (4.0)	9 (3.8)	1.00
Heaviness in the legs	3 (2.6)	6 (4.8)	9 (3.8)	.505
Increased blood pressure	5 (4.4)	3 (2.4)	8 (3.3)	.483
Decreased appetite	4 (3.5)	3 (2.4)	7 (2.9)	.711
Dry mouth	4 (3.5)	3 (2.4)	7 (2.9)	.711
Hypersalivation	3 (2.6)	4 (3.2)	7 (2.9)	1.00
Conversion symptoms	4 (3.5)	2 (1.6)	6 (2.5)	.427
Seborrhea	3 (2.6)	3 (2.4)	6 (2.5)	1.00
Allergic reactions	3 (2.6)	2 (1.6)	5 (2.1)	.671
Hypotonia	2 (1.8)	2 (1.6)	4 (1.7)	
Increased hypertension	2 (1.8)	2 (1.6)	4 (1.7)	
Micturition difficulties	2 (1.8)	2 (1.6)	4 (1.7)	
Ataxia	0 (0.0)	3 (2.4)	3 (1.3)	
Dependent edema	3 (2.6)	0 (0.0)	3 (1.3)	
Menstrual difficulties	1 (0.9)	2 (1.6)	3 (1.3)	
Akathisia	1 (0.9)	1 (0.8)	2 (0.8)	
Hypokinesia	1 (0.9)	1 (0.8)	2 (0.8)	
Acute dyskinesia	0 (0.0)	1 (0.8)	1 (0.4)	

*p-Value is from Fisher's Exact test.
 Program: RMP.F1JSHMBU.SASPGM(FQAESS1C) QCA700
 Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL

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