

CONFIDENTIAL

LY248686

Regulatory Response

**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
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OPATIENTS WITH ≥ 1 TESS	60 (74.1)	164 (81.2)	224 (79.2)	.197
Dizziness	24 (29.6)	69 (34.2)	93 (32.9)	.487
Increased dreams/nightmares	19 (23.5)	32 (15.8)	51 (18.0)	.170
Nausea	6 ( 7.4)	35 (17.3)	41 (14.5)	.039
Excessive appetite	10 (12.3)	27 (13.4)	37 (13.1)	1.00
Blurred vision	10 (12.3)	25 (12.4)	35 (12.4)	1.00
Diarrhea	3 ( 3.7)	28 (13.9)	31 (11.0)	.011
Headache	5 ( 6.2)	25 (12.4)	30 (10.6)	.140
Difficulty falling asleep	5 ( 6.2)	24 (11.9)	29 (10.2)	.195
Drowsiness	7 ( 8.6)	22 (10.9)	29 (10.2)	.668
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)	12 ( 5.9)	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.F1JSHMCQ.SASPGM(FQAESS1C) QCA700  
Data: RMP.SAS.F1JM.L.MCHMCQSW.FINAL

Exhibit 10  
302  
Witness: Wolpinich  
Date: 4/30/15 MKG

CYM-00149293

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Regulatory Response

1PRODUCTION DATA - PRODUCTION MODE

Friday, 11 June 2004 PAGE: 2

Treatment-Emergent Adverse Events Collected by AMDP-5

By Decreasing Frequency

All Patients who Entered Study Period IV

PLJ-MC-HMCQ Study Period IV

	DULOX N=81 n(%)	VENLAPAX 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	2 ( 2.5)	10 ( 5.0)	12 ( 4.2)	.519
Ataxia	3 ( 3.7)	8 ( 4.0)	11 ( 3.9)	1.00
Decreased libido	5 ( 6.2)	4 ( 2.0)	9 ( 3.2)	.125
Micturition difficulties	3 ( 3.7)	6 ( 3.0)	9 ( 3.2)	.719
Dependent edema	1 ( 1.2)	6 ( 3.0)	7 ( 2.5)	.677
Increased blood pressure	1 ( 1.2)	6 ( 3.0)	7 ( 2.5)	.677
Akathisia	1 ( 1.2)	5 ( 2.5)	6 ( 2.1)	.677
Hypersalivation	0 ( 0.0)	6 ( 3.0)	6 ( 2.1)	.187
Seborrhea	2 ( 2.5)	4 ( 2.0)	6 ( 2.1)	1.00
Cardiac pain	1 ( 1.2)	3 ( 1.5)	4 ( 1.4)	
Myotagmus	1 ( 1.2)	3 ( 1.5)	4 ( 1.4)	
Acute dyskinesia	0 ( 0.0)	3 ( 1.5)	3 ( 1.1)	
Menstrual difficulties	2 ( 2.5)	1 ( 0.5)	3 ( 1.1)	
Allergic reactions	1 ( 1.2)	1 ( 0.5)	2 ( 0.7)	
Hypokinesia	0 ( 0.0)	2 ( 1.0)	2 ( 0.7)	
Increased hypertension	1 ( 1.2)	1 ( 0.5)	2 ( 0.7)	
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.F1JSEMCQ.SASPGM(FQAESS1C) QCA700

Data: RMP.SAS.F1JM.L.MCHMCQSW.FINAL

CYM-00149294