Cymbalta (Duloxetine hydrochloride)

Supportive Optional Document to the Duloxetine Core Data Sheet Pre-Read Based on Clinical Trial Data in the Adult Population

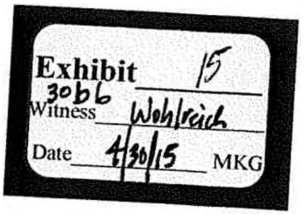
Data from April 2010 through October 2011

Eli Lilly and Company

CONFIDENTIAL TO REGULATORY AGENCIES

Document Electronically Approved by Lilly on date provided below.

Pavel Vohlidka
Senior Director
Global Patient Safety
Lilly Corporate Center
Indianapolis, Indiana 46285



Approval Date: 06-Mar-2012 GMT

1. Table of Contents

Table of Contents

2. Summary of Trials and Databases

Table 2.1. Summary of Studies Included in this Analysis Since the Previous Database Integration

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-US-HMEZ	4	An Open-Label Randomized Comparison of Duloxetine to Pregabalin, and the Combination of Duloxetine and Gabapentin Among Patients with Inadequate Response to Gabapentin for the Management of Diabetic Peripheral Neuropathic Pain	DPNP	Open Label, Parallel Assignment, Randomized, Uncontrolled, Safety/Efficacy Study	**Pregabalin:** 50 mg TID (US & Germany) or 75 mg BID (Canada) for 2 weeks, then pregabilin 100 mg TID (US & Germany) or 150 mg BID (Canada) for 10 weeks **Duloxetine:** 30 mg QD for 1 week, then 60 mg QD for 11 weeks **Gabapentin/ Duloxetine:** Stable gabapentin plus duloxetine 30 mg QD for 1 week, then stable gabapentin plus duloxetine 60 mg QD for 11 weeks	Pregabalin N=134 Duloxetine N=138 Gabapentin/Duloxetine N=135	Pregabalin: 134 (76/58) Duloxetine: 138 (83/55) Gabapentin/ Duloxetine: 135 (83/52)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-BI-HMGN	4	A 12-Week, Open-Label, Two Parallel Groups Study to Assess the Efficacy of Orally Administered Duloxetine 60 mg and 120 mg Per Day on Treatment Outcomes in Patients with Diabetic Peripheral Neuropathic Pain with or without Co-Morbid Major Depressive Disorder	DPNP	Open Label, Parallel Assignment Non-Randomized Safety/Efficacy Study	**DPNP with depression:** duloxetine 60 mg for 12 weeks, with the option to dose escalate up to duloxetine 120 mg for non-responders **DPNP without depression:** duloxetine 60 mg for 12 weeks, with the option to dose escalate up to duloxetine 120 mg for non-responders	DPNP with depression N=30 DPNP without depression N=78	DPNP with depression: 30 (15/15) DPNP without depression: 78 (42/36)
F1J-IT-HMFQ	4	An Open Label Pilot Study on the Tolerability of Duloxetine in the Treatment of Depressed Patients with Parkinson's Disease	MDD	Open Label, Single Group Assignment, Uncontrolled, Pilot Trial	**Duloxetine 60 mg:** duloxetine 30 mg QD for 1 week, duloxetine 60 mg QD for 11 weeks	Duloxetine 60 mg N=151	Duloxetine 60 mg: 151 (66/85)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-MC-HMFL	4	A Phase 4 Comparison of Duloxetine Dosing Strategies in the Treatment of Korean Patients with Major Depressive Disorder	MDD	Open Label, Multicenter, Randomized, Parallel Assignment	**Initial dosing phase of 1 week:** Duloxetine 30mg with food, Duloxetine 60 mg with food, duloxetine 30 mg, duloxetine 60 mg, followed by **acute phase** of 7 weeks where duloxetine 60 mg QD may be taken without regard for food.	Duloxetine 30 mg with food N=63 Duloxetine 60 mg with food N=59 Duloxetine 30 mg without food N=64 Duloxetine 60 mg without food N=63	Duloxetine 30 mg with food: 63(16/47) Duloxetine 60 mg with food: 59 (16/43) Duloxetine 30 mg without food: 64 (24/40) Duloxetine 60 mg without food: 63 (16/47)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-EW-HMGD	4	Comparison of Two Different Treatment Strategies in Patients with Major Disorder Not Exhibiting Improvement on Escitalopram	MDD	Double Blind, Randomized, Parallel Assignment	**Early Intervention:** escitalopram 10 mg QC for 4 weeks followed by duloxetine flexible dose (60 or 120 mg QD) for 12 weeks. **Delayed Intervention:** escitalopram 10 mg QD for 4 weeks followed by escitalopram 10-20 mg QD for 4 weeks. Then non-responders switched to duloxetine flexible dose (60 or 120 mg QD) for 8 weeks. Responders continued escitalopram 10 to 20 mg daily for 8 weeks.	Early intervention N=282 Delayed intervention N=284	Early intervention: 282 (86/196) Delayed intervention: 284 (87/197)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-CR-HMGM	4	A Phase 4, 8-Week, Double-blind, Randomized Study Comparing Switching to Duloxetine or Escitalopram in Patients With Major Depressive Disorder and Residual Apathy in the Absence of Depressed Mood	MDD	Double Blind, Randomized, Parallel Assignment	**Duloxetine:** duloxetine 60 mg QD for 1 week (Acute Treatment) followed by duloxetine 60-120 mg QD for 7 weeks (Optimization), with an option to continue treatment for an additional 2 weeks. **Escitalopram:** escitalopram 10 mg QD for 1 week (Acute Treatment), followed by escitalopram 10-20 mg QD for 7 weeks (Optimization), with an option to continue treatment for an additional 2 weeks.	Duloxetine N=244 Escitalopram N=239	Duloxetine: 244(57/187) Escitalopram: 239 (60/179)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
FIJ-CR-S022	4	Attributes of Response in Depressed Patients Switched to Treatment with Duloxetine (ARDENT Study)	MDD	Open Label, Parallel Assignment, Active Control	**Responders:** duloxetine 60 mg QD for 4 weeks, followed by duloxetine 60 mg QD for 4 more weeks. **Non-responders:** duloxetine 60 mg QD for 4 weeks, followed by duloxetine 120 mg QD for 4 more weeks. **Unclassified:** duloxetine 60 mg QD for 4 weeks (Study Period II) with unknown response status.	Responders N=115 Non-responders N=91 Unclassified N=36	Responders: 115 (27/88) Non-responders: 91 (27/64) Unclassified: 36 (6/30)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-MC-HMGP	3b	Duloxetine 60 mg Once Daily Versus Placebo in the Treatment of Patients with Osteoarthritis Knee Pain	OA	Multicenter, Double-Blind, Randomized, Placebo-Controlled	**Planned:** **Duloxetine:** 60 mg duloxetine QD for 12 weeks. **Placebo** **Actual (due to an error in study drug administration:** **Duloxetine:** 30 mg duloxetine for 1 week, followed by placebo for 12 weeks. **Placebo:** placebo for 1 week, followed by 60 mg duloxetine for 12 weeks.	Duloxetine-Placebo N=207 Placebo-Duloxetine N=217	Duloxetine-Placebo: 207 (60/147) Placebo-Duloxetine: 217 (76/141)
F1J-US-HMGL	3b	A Randomized, Placebo-Controlled Trial of Duloxetine Added to Nonsteroidal Anti-inflammatory Drugs in Patients with Knee Pain due to Osteoarthritis who have had Suboptimal Response to Nonsteroidal Anti-inflammatory Drug Treatment	OA	Multicenter, Double-Blind, Randomized, Placebo-Controlled	**Duloxetine:** 30 mg QD for 1 week escalating to 60 mg QD thereafter, with possibility of dose escalation to 120 mg, for 10 weeks **Placebo**	Duloxetine N=264 Placebo N=260	Duloxetine: 264 (112/152) Placebo: 260 (113/147)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-MC-HMGG	4	A Randomized, Double-Blind Comparison of Duloxetine 30 mg QD and Placebo in Adult Patients with Fibromyalgia	Fibromyalgia	Multicenter, Double-Blind, Parallel, Randomized, Placebo-Controlled	**Duloxetine:** 30 mg QD for 12 weeks **Placebo**	Duloxetine N=155 Placebo N=153	Duloxetine: 155 (9/146) Placebo: 153 (6/147)
F1J-US-HMFR	3b	Duloxetine in Patients with Central Neuropathic Pain Due to Multiple Sclerosis	Multiple Sclerosis	Multicenter Double-Blind, Randomized, Parallel Group, Placebo-Controlled	**Duloxetine:** 60 mg QD for 6 weeks (Acute) followed by 12-week extension phase with dose escalation in 30 mg increments to duloxetine 90 mg or 120 mg. **Placebo**	Duloxetine N=118 Placebo N=121	Duloxetine: 118 (32/86) Placebo: 121 (28/93)
F1J-MC-HMFJ	3	Duloxetine versus Placebo in the Treatment of Patients with Generalized Anxiety Disorder in China	GAD	Multicenter, Double-Blind, Randomized, Placebo-Controlled	**Duloxetine:** 60 mg QD, with possibility of dose escalation to 120 mg, for 15 weeks **Placebo**	Duloxetine N=108 Placebo N=102	Duloxetine: 108 (58/50) Placebo: 102 (46/56)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-US-HMFA	4	Duloxetine Versus Placebo in the Long-Term Treatment of Patients with Late-Life Major Depression	MDD	Multicenter, Parallel-Design Double-Blind, Randomized, Placebo-Controlled	**Duloxetine:** 1 week placebo before randomization, 30 mg duloxetine QD for 1 week, then 60 mg QD for 13 weeks (Acute), followed by double-blind continuation/treatment-optimization/placebo-rescue period where patients in the placebo group could switch to duloxetine therapy (30 mg QD for 1 week followed by 60 mg QD for the remainder), and patients in the duloxetine group were eligible for dose escalation up to 120 mg QD. **Placebo**	Duloxetine N=249 Placebo N=121	Duloxetine: 249 (86/163) Placebo: 121 (50/71)

Study Code	Phase	Study Title	Indication	Study Design	Dosing/ Frequency/ Regimen	Number of Patients in Treatment Group	Subject/Patient Exposure per Treatment Group (M/F)
F1J-US-HMGR	4	A Phase 4, 8-Week, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy of Duloxetine 60 mg Once Daily in Outpatients with Major Depressive Disorder and Associated Painful Physical Symptoms	MDD	Multicenter, Double-Blind, Randomized, Parallel, Placebo-Controlled	**Duloxetine:** 30 mg QD for 1 week, 60 mg QD for 7 weeks, with an optional blinded taper phase for 2 weeks **Placebo**	Duloxetine N=262 Placebo N=266	Duloxetine: 262 (82/180) Placebo: 266 (82/184)
F1J-US-HMGU	4	A Phase 4, 8-Week, Double-blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy of Duloxetine 60 mg Once Daily in Outpatients with Major Depressive Disorder and Associated Painful Physical Symptoms	MDD	Multicenter, Double-Blind, Parallel, Randomized, Placebo-Controlled, Fixed-Dose	**Duloxetine:** 30 mg QD for 1 week, 60 mg QD for 7 weeks, with an optional blinded taper phase for 2 weeks **Placebo**	Duloxetine N=261 Placebo N=266	Duloxetine: 261 (78/183) Placebo: 266 (88/178)

Table 2.2. Studies Included in the All Placebo-Controlled Analyses Set as of Previous Database Integration on 23 April 2010

Indication	Study Codes
OA	F1J-MC-HMFG, F1J-MC-HMEP
CLBP	F1J-MC-HMEO, F1J-MC-HMGC, F1J-MC-HMEN (acute)
Fibromyalgia	F1J-MC-HMCA, F1J-MC-HMBO, F1J-MC-HMEF, F1J-MC-HMCJ, F1J-US-HMGB
GAD	F1J-MC-HMBR, F1J-MC-HMDT, F1J-MC-HMDU, F1J-MC-HMDW
DPNP	F1J-MC-HMAVa (acute), F1J-MC-HMAVb (acute), F1J-MC-HMAW (acute), F1J-MC-HMEQ
MDD	F1J-MC-HMAG, F1J-MC-HMAH, F1J-MC-HMAI, F1J-MC-HMAQa, F1J-MC-HMAQb, F1J-MC-HMATa, F1J-MC-HMATb, F1J-MC-HMAYa, F1J-MC-HMQYb, F1J-MC-HMBHa, F1J-MC-HMBHb, F1J-MC-HMBV, F1J-US-HMCB, F1J-US-HMCR, F1J-MC-HQAC (also referred to as H8I-MC-HQAC), F1J-BI-HMDH, F1J-US-HMFS
SUI	F1J-MC-SAAW, F1J-MC-SBAB (acute), F1J-MC-SBAF (acute), F1J-MC-SBAM (acute), F1J-MC-SBAT, F1J-MC-SBAV, F1J-MC-SBAX, F1J-MC-SBBA, F1J-EW-SBCC, F1J-MC-SBBR (acute), F1J-MC-SBBT, F1J-MC-SBBU, F1J-MC-SAAI, F1J-MC-SAAL, F1J-MC-SBCM
Other LUTD	F1J-MC-SAAA, F1J-MC-SAAB, F1J-MC-SAAH, F1J-MC-SBBL, F1J-MC-SBBO (acute)

Abbreviations: CLBP = chronic low back pain; DPNP = diabetic peripheral neuropathic pain; GAD = general anxiety disorder; LUTD = lower urinary tract disorder; MDD = major depressive disorder; OA=osteoarthritis of the knee; SUI = stress urinary incontinence.

Table 2.3. **Studies Included in the Overall Duloxetine Exposures Analyses Set as of Previous Database Integration on 23 April 2010**

Indication	Study Codes
OA	F1J-MC-HMFG, F1J-MC-HMEP
CLBP	F1J-MC-HMEO, F1J-MC-HMGC, F1J-MC-HMEN (acute), F1J-MC-HMEN (extension)
Fibromyalgia	F1J-MC-HMCA, F1J-MC-HMBO, F1J-MC-HMEF, F1J-MC-HMCJ, F1J-MC-HMEH, F1J, US-HMGB
GAD	F1J-MC-HMBR, F1J-MC-HMDT, F1J-MC-HMDU, F1J-MC-HMDW, F1J-MC-HMDV
DPNP	F1J-MC-HMEM, F1J-MC-HMEQ, F1J-MC-HMAVa (acute), F1J-MC-HMAVb (acute), F1J-MC-HMAW (acute), F1J-MC-HMAVa (extension), F1J-MC-HMAVb (extension), F1J-MC-HMAW (extension), F1J-MC-HMBT, F1J-MC-HMDY
MDD	F1J-MC-HMAG, F1J-MC-HMAH, F1J-MC-HMAI, F1J-MC-HMAQa, F1J-MC-HMAQb, F1J-MC-HMATa, F1J-MC-HMATb, F1J-MC-HMAYa, F1J-MC-HMAYb, F1J-MC-HMBHa, F1J-MC-HMBHb, F1J-MC-HMBV, F1J-US-HMCB, F1J-US-HMCR, F1J-MC-HQAC (also referred to as H8I-MC-HQAC), F1J-BI-HMDH, F1J-EW-E001, F1J-MC-HMAU, F1J-MC-HMBC, F1J-MC-HMBU, F1J-US-HMBY, F1J-US-HMBZ, F1J-MC-HMCM, F1J-MC-HMCQ, F1J-AA-HMCV, F1J-MC-HMCX, F1J-MC-HMCY, F1J-AY-HMCZ, F1J-MC-HMDD, F1J-MC-HMDG, F1J-MC-HMDG/HMED, F1J-US-HMDR, F1J-US-HMFT, F1J-MC-HMDI, F1J-BI-HMES, F1J-US-HMFS
SUI	F1J-MC-SAAW, F1J-MC-SBAB (acute), F1J-MC-SBAF (acute), F1J-MC-SBAM (acute), F1J-MC-SBAT, F1J-MC-SBAV, F1J-MC-SBAX, F1J-MC-SBBA, F1J-EW-SBCC, F1J-MC-SBBR (acute), F1J-MC-SBBT, F1J-MC-SBBU, F1J-MC-SAAI, F1J-MC-SAAL, F1J-MC-SBAB (extension), F1J-MC-SBAF (extension), F1J-MC-SBAM (extension), F1J-MC-SBBR (extension), F1J-EW-SBCC (extension), F1J-MC-SBAV/SBAW, F1J-MC-SBAT/SBAU, F1J-MC-SBAX/SBBM, F1J-MC-SBAY, F1J-MC-SBCT, F1J-US-SBCD, F1J-BI-SBCM
Other LUTD	F1J-MC-SAAA, F1J-MC-SAAB, F1J-MC-SAAH, F1J-MC-SBBL, F1J-MC-SBBO (acute), F1J-MC-SBBO (extension), F1J-MC-SBBX
MDD, DPNP, GAD and FMS	F1J-MC-HMCN

Abbreviations: DPNP = diabetic peripheral neuropathic pain; GAD = general anxiety disorder; LUTD = lower urinary tract disorder; MDD = major depressive disorder; OA = osteoarthritis of the knee; SUI = stress urinary incontinence.

Table 3.5. Taper Discontinuation-Emergent Adverse Events, All Patients Who Entered Drug-Tapering Phase, All Placebo-Controlled Analyses Set, for Current Database Lock on 19 October 2011

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Patients with >= 1 Discontinuation-Emergent Adverse Event	302 (11.0)	597 (18.6)	899 (15.1)	<.001	<.001	A C
Dizziness	12 (0.4)	116 (3.6)	128 (2.2)	<.001	<.001	A B
Headache	34 (1.2)	62 (1.9)	96 (1.6)	.069	.039	
Nausea	14 (0.5)	67 (2.1)	81 (1.4)	<.001	<.001	A B
Diarrhoea	7 (0.3)	35 (1.1)	42 (0.7)	<.001	<.001	A B
Insomnia	6 (0.2)	36 (1.1)	42 (0.7)	<.001	<.001	A B
Nasopharyngitis	11 (0.4)	22 (0.7)	33 (0.6)	.152	.163	
Influenza	10 (0.4)	15 (0.5)	25 (0.4)	.511	.688	
Upper respiratory tract infection	14 (0.5)	11 (0.3)	25 (0.4)	.630	.323	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Fatigue	7 (0.3)	17 (0.5)	24 (0.4)	.334	.105	B
Vertigo	4 (0.1)	20 (0.6)	24 (0.4)	.006	.004	A B
Paraesthesia	3 (0.1)	19 (0.6)	22 (0.4)	.003	.002	A B
Anxiety	6 (0.2)	15 (0.5)	21 (0.4)	.185	.127	B
Sinusitis	12 (0.4)	8 (0.2)	20 (0.3)	.463	.262	
Vomiting	3 (0.1)	16 (0.5)	19 (0.3)	.020	.010	A B
Cough	7 (0.3)	11 (0.3)	18 (0.3)	.667	.639	
Hyperhidrosis	5 (0.2)	13 (0.4)	18 (0.3)	.075	.156	B
Arthralgia	8 (0.3)	8 (0.2)	16 (0.3)	.541	.805	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Back pain	6 (0.2)	9 (0.3)	15 (0.3)	.320	.797	
Irritability	4 (0.1)	11 (0.3)	15 (0.3)	.187	.194	B
Abdominal pain	8 (0.3)	6 (0.2)	14 (0.2)	.407	.433	
Muscle spasms	5 (0.2)	9 (0.3)	14 (0.2)	.381	.594	
Myalgia	2 (0.1)	12 (0.4)	14 (0.2)	.038	.028	A B
Bronchitis	5 (0.2)	8 (0.2)	13 (0.2)	.661	.782	
Abnormal dreams	1 (0.0)	11 (0.3)	12 (0.2)	.022	.008	A B
Depression	0 (0)	12 (0.4)	12 (0.2)	<.001	<.001	A
Pain	4 (0.1)	8 (0.2)	12 (0.2)	.287	.564	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Urinary tract infection	6 (0.2)	6 (0.2)	12 (0.2)	.700	.781	
Asthenia	3 (0.1)	8 (0.2)	11 (0.2)	.317	.242	B
Dry mouth	5 (0.2)	6 (0.2)	11 (0.2)	.948	1.000	
Oedema peripheral	5 (0.2)	6 (0.2)	11 (0.2)	.777	1.000	
Oropharyngeal pain	4 (0.1)	7 (0.2)	11 (0.2)	.452	.563	
Pain in extremity	4 (0.1)	7 (0.2)	11 (0.2)	.666	.563	
Pruritus	4 (0.1)	7 (0.2)	11 (0.2)	.512	.563	
Tinnitus	3 (0.1)	8 (0.2)	11 (0.2)	.253	.242	B
Abdominal discomfort	5 (0.2)	5 (0.2)	10 (0.2)	.769	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Dyspepsia	2 (0.1)	8 (0.2)	10 (0.2)	.166	.120	B
Hypertension	0 (0)	10 (0.3)	10 (0.2)	.017	.003	A
Musculoskeletal pain	3 (0.1)	7 (0.2)	10 (0.2)	.258	.359	
Abdominal pain upper	2 (0.1)	7 (0.2)	9 (0.2)	.085	.192	B
Hot flush	0 (0)	9 (0.3)	9 (0.2)	.008	.005	A
Seasonal allergy	3 (0.1)	6 (0.2)	9 (0.2)	.380	.520	
Somnolence	3 (0.1)	6 (0.2)	9 (0.2)	.790	.520	
Tremor	0 (0)	9 (0.3)	9 (0.2)	.006	.005	A
Constipation	3 (0.1)	4 (0.1)	7 (0.1)	.821	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Flatulence	4 (0.1)	3 (0.1)	7 (0.1)	.663	.710	
Nightmare	0 (0)	7 (0.2)	7 (0.1)	.025	.018	A
Contusion	1 (0.0)	5 (0.2)	6 (0.1)	.169	.227	B
Fall	3 (0.1)	3 (0.1)	6 (0.1)	.818	1.000	
Gamma-glutamyltransferase increased	2 (0.1)	4 (0.1)	6 (0.1)	.488	.693	
Gastroenteritis	3 (0.1)	3 (0.1)	6 (0.1)	.657	1.000	
Gastroenteritis viral	5 (0.2)	1 (0.0)	6 (0.1)	.153	.101	
Pyrexia	1 (0.0)	5 (0.2)	6 (0.1)	.119	.227	B
Disturbance in attention	2 (0.1)	3 (0.1)	5 (0.1)	.615	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Dysuria	2 (0.1)	3 (0.1)	5 (0.1)	.955	1.000	
Ear infection	4 (0.1)	1 (0.0)	5 (0.1)	.224	.187	
Hypoaesthesia	1 (0.0)	4 (0.1)	5 (0.1)	.277	.383	B
Influenza like illness	1 (0.0)	4 (0.1)	5 (0.1)	.194	.383	B
Labyrinthitis	0 (0)	5 (0.2)	5 (0.1)	.036	.066	A
Nasal congestion	3 (0.1)	2 (0.1)	5 (0.1)	.765	.667	
Palpitations	0 (0)	5 (0.2)	5 (0.1)	.032	.066	A
Sinus congestion	1 (0.0)	4 (0.1)	5 (0.1)	.196	.383	B
Tearfulness	3 (0.1)	2 (0.1)	5 (0.1)	.570	.667	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Toothache	0 (0)	5 (0.2)	5 (0.1)	.011	.066	A
Blood glucose increased	2 (0.1)	2 (0.1)	4 (0.1)	.819	1.000	
Blood pressure increased	1 (0.0)	3 (0.1)	4 (0.1)	.267	.630	B
Decreased appetite	2 (0.1)	2 (0.1)	4 (0.1)	.867	1.000	
Dermatitis contact	1 (0.0)	3 (0.1)	4 (0.1)	.665	.630	B
Dyslipidaemia	2 (0.1)	2 (0.1)	4 (0.1)	.948	1.000	
Gastritis	2 (0.1)	2 (0.1)	4 (0.1)	.654	1.000	
Hypercholesterolaemia	2 (0.1)	2 (0.1)	4 (0.1)	.480	1.000	
Increased appetite	1 (0.0)	3 (0.1)	4 (0.1)	.572	.630	B

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Initial insomnia	2 (0.1)	2 (0.1)	4 (0.1)	.897	1.000	
Menorrhagia	1 (0.0)	3 (0.1)	4 (0.1)	.462	.630	B
Procedural pain	1 (0.0)	3 (0.1)	4 (0.1)	.275	.630	B
Tooth infection	2 (0.1)	2 (0.1)	4 (0.1)	.927	1.000	
Viral infection	1 (0.0)	3 (0.1)	4 (0.1)	.469	.630	B
Alanine aminotransferase increased	0 (0)	3 (0.1)	3 (0.1)	.088	.255	
Arthritis	2 (0.1)	1 (0.0)	3 (0.1)	.521	.598	
Cataract operation	3 (0.1)	0 (0)	3 (0.1)	.030	.097	
Chest discomfort	1 (0.0)	2 (0.1)	3 (0.1)	.628	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Chest pain	3 (0.1)	0 (0)	3 (0.1)	.076	.097	
Chills	1 (0.0)	2 (0.1)	3 (0.1)	.562	1.000	
Conjunctivitis	0 (0)	3 (0.1)	3 (0.1)	.114	.255	
Cystitis	2 (0.1)	1 (0.0)	3 (0.1)	.461	.598	
Depressed mood	0 (0)	3 (0.1)	3 (0.1)	.165	.255	
Diabetes mellitus	0 (0)	3 (0.1)	3 (0.1)	.233	.255	
Dysmenorrhoea	2 (0.1)	1 (0.0)	3 (0.1)	.635	.598	
Emotional disorder	1 (0.0)	2 (0.1)	3 (0.1)	.873	1.000	
Feeling hot	0 (0)	3 (0.1)	3 (0.1)	.108	.255	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Feeling jittery	2 (0.1)	1 (0.0)	3 (0.1)	.524	.598	
Fibromyalgia	2 (0.1)	1 (0.0)	3 (0.1)	.288	.598	
Flushing	1 (0.0)	2 (0.1)	3 (0.1)	.925	1.000	
Fungal infection	2 (0.1)	1 (0.0)	3 (0.1)	.626	.598	
Haemorrhoids	2 (0.1)	1 (0.0)	3 (0.1)	.633	.598	
Hepatic enzyme increased	0 (0)	3 (0.1)	3 (0.1)	.161	.255	
Hypersensitivity	0 (0)	3 (0.1)	3 (0.1)	.111	.255	
Lethargy	0 (0)	3 (0.1)	3 (0.1)	.130	.255	
Neck pain	2 (0.1)	1 (0.0)	3 (0.1)	.848	.598	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q3llsidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Night sweats	0 (0)	3 (0.1)	3 (0.1)	.113	.255	
Osteoarthritis	0 (0)	3 (0.1)	3 (0.1)	.228	.255	
Pneumonia	2 (0.1)	1 (0.0)	3 (0.1)	.455	.598	
Rash	1 (0.0)	2 (0.1)	3 (0.1)	.542	1.000	
Sinus headache	0 (0)	3 (0.1)	3 (0.1)	.045	.255	A
Sleep disorder	1 (0.0)	2 (0.1)	3 (0.1)	.965	1.000	
Spinal osteoarthritis	1 (0.0)	2 (0.1)	3 (0.1)	.996	1.000	
Tachycardia	1 (0.0)	2 (0.1)	3 (0.1)	.658	1.000	
Tension headache	1 (0.0)	2 (0.1)	3 (0.1)	.536	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Urticaria	1 (0.0)	2 (0.1)	3 (0.1)	.539	1.000	
Vision blurred	0 (0)	3 (0.1)	3 (0.1)	.108	.255	
Weight increased	1 (0.0)	2 (0.1)	3 (0.1)	.382	1.000	
Abdominal distension	0 (0)	2 (0.1)	2 (0.0)	.234	.503	
Aggression	1 (0.0)	1 (0.0)	2 (0.0)	.883	1.000	
Agitation	1 (0.0)	1 (0.0)	2 (0.0)	.918	1.000	
Amnesia	0 (0)	2 (0.1)	2 (0.0)	.347	.503	
Anaemia	0 (0)	2 (0.1)	2 (0.0)	.318	.503	
Apathy	1 (0.0)	1 (0.0)	2 (0.0)	.606	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Aspartate aminotransferase increased	1 (0.0)	1 (0.0)	2 (0.0)	.816	1.000	
Asthma	0 (0)	2 (0.1)	2 (0.0)	.231	.503	
Benign prostatic hyperplasia	2 (0.1)	0 (0)	2 (0.0)	.049	.212	
Blepharitis	2 (0.1)	0 (0)	2 (0.0)	.109	.212	
Blood alkaline phosphatase increased	0 (0)	2 (0.1)	2 (0.0)	.227	.503	
Blood bilirubin increased	1 (0.0)	1 (0.0)	2 (0.0)	.971	1.000	
Blood creatine phosphokinase increased	1 (0.0)	1 (0.0)	2 (0.0)	1.000	1.000	
Breast pain	0 (0)	2 (0.1)	2 (0.0)	.112	.503	
Bursitis	0 (0)	2 (0.1)	2 (0.0)	.205	.503	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Cellulitis	1 (0.0)	1 (0.0)	2 (0.0)	.883	1.000	
Dehydration	1 (0.0)	1 (0.0)	2 (0.0)	.769	1.000	
Disorientation	0 (0)	2 (0.1)	2 (0.0)	.144	.503	
Dysphonia	1 (0.0)	1 (0.0)	2 (0.0)	.813	1.000	
Dyspnoea	1 (0.0)	1 (0.0)	2 (0.0)	.932	1.000	
Ear discomfort	0 (0)	2 (0.1)	2 (0.0)	.231	.503	
Ear pain	2 (0.1)	0 (0)	2 (0.0)	.245	.212	
Epistaxis	1 (0.0)	1 (0.0)	2 (0.0)	.831	1.000	
Eye pain	1 (0.0)	1 (0.0)	2 (0.0)	.929	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Feeling abnormal	0 (0)	2 (0.1)	2 (0.0)	.141	.503	
Feeling of body temperature change	0 (0)	2 (0.1)	2 (0.0)	.156	.503	
Gastrointestinal pain	1 (0.0)	1 (0.0)	2 (0.0)	.850	1.000	
Gastrooesophageal reflux disease	0 (0)	2 (0.1)	2 (0.0)	.221	.503	
Glycosylated haemoglobin increased	1 (0.0)	1 (0.0)	2 (0.0)	.977	1.000	
Heart rate increased	0 (0)	2 (0.1)	2 (0.0)	.215	.503	
Hepatic steatosis	0 (0)	2 (0.1)	2 (0.0)	.340	.503	
Herpes zoster	0 (0)	2 (0.1)	2 (0.0)	.126	.503	
Hyperglycaemia	0 (0)	2 (0.1)	2 (0.0)	.222	.503	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Hypertonia	1 (0.0)	1 (0.0)	2 (0.0)	.790	1.000	
Hyperuricaemia	0 (0)	2 (0.1)	2 (0.0)	.143	.503	
Hypothyroidism	0 (0)	2 (0.1)	2 (0.0)	.231	.503	
Joint effusion	0 (0)	2 (0.1)	2 (0.0)	.347	.503	
Laceration	1 (0.0)	1 (0.0)	2 (0.0)	.572	1.000	
Libido decreased	1 (0.0)	1 (0.0)	2 (0.0)	.793	1.000	
Liver function test abnormal	0 (0)	2 (0.1)	2 (0.0)	.140	.503	
Micturition urgency	0 (0)	2 (0.1)	2 (0.0)	.200	.503	
Migraine	0 (0)	2 (0.1)	2 (0.0)	.160	.503	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Mood swings	0 (0)	2 (0.1)	2 (0.0)	.141	.503	
Muscle contracture	1 (0.0)	1 (0.0)	2 (0.0)	.730	1.000	
Muscular weakness	0 (0)	2 (0.1)	2 (0.0)	.322	.503	
Nervousness	0 (0)	2 (0.1)	2 (0.0)	.141	.503	
Otitis media	1 (0.0)	1 (0.0)	2 (0.0)	.835	1.000	
Panic attack	1 (0.0)	1 (0.0)	2 (0.0)	.730	1.000	
Piriformis syndrome	0 (0)	2 (0.1)	2 (0.0)	.337	.503	
Pollakiuria	2 (0.1)	0 (0)	2 (0.0)	.223	.212	
Productive cough	1 (0.0)	1 (0.0)	2 (0.0)	.982	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Psychomotor hyperactivity	0 (0)	2 (0.1)	2 (0.0)	.127	.503	
Restlessness	1 (0.0)	1 (0.0)	2 (0.0)	.796	1.000	
Rhinitis	1 (0.0)	1 (0.0)	2 (0.0)	.632	1.000	
Rib fracture	0 (0)	2 (0.1)	2 (0.0)	.153	.503	
Road traffic accident	1 (0.0)	1 (0.0)	2 (0.0)	.961	1.000	
Scar	0 (0)	2 (0.1)	2 (0.0)	.337	.503	
Serotonin syndrome	0 (0)	2 (0.1)	2 (0.0)	.237	.503	
Sneezing	0 (0)	2 (0.1)	2 (0.0)	.323	.503	
Swelling face	0 (0)	2 (0.1)	2 (0.0)	.152	.503	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Syncope	1 (0.0)	1 (0.0)	2 (0.0)	.858	1.000	
Tendonitis	1 (0.0)	1 (0.0)	2 (0.0)	.915	1.000	
Tooth abscess	0 (0)	2 (0.1)	2 (0.0)	.226	.503	
Vaginal infection	0 (0)	2 (0.1)	2 (0.0)	.201	.503	
Vulvovaginal mycotic infection	0 (0)	2 (0.1)	2 (0.0)	.217	.503	
Abdominal tenderness	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Abnormal sensation in eye	0 (0)	1 (0.0)	1 (0.0)	.279	1.000	
Allergic cough	1 (0.0)	0 (0)	1 (0.0)	.166	.460	
Alopecia	1 (0.0)	0 (0)	1 (0.0)	.325	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Anger	0 (0)	1 (0.0)	1 (0.0)	.272	1.000	
Animal bite	0 (0)	1 (0.0)	1 (0.0)	.331	1.000	
Ankle fracture	0 (0)	1 (0.0)	1 (0.0)	.323	1.000	
Areflexia	1 (0.0)	0 (0)	1 (0.0)	.140	.460	
Arthropathy	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Arthropod sting	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Autonomic nervous system imbalance	0 (0)	1 (0.0)	1 (0.0)	.315	1.000	
Balance disorder	0 (0)	1 (0.0)	1 (0.0)	.514	1.000	
Benign colonic neoplasm	1 (0.0)	0 (0)	1 (0.0)	.335	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Blood cholesterol increased	0 (0)	1 (0.0)	1 (0.0)	.331	1.000	
Blood creatine increased	0 (0)	1 (0.0)	1 (0.0)	.317	1.000	
Blood potassium decreased	0 (0)	1 (0.0)	1 (0.0)	.331	1.000	
Blood triglycerides increased	1 (0.0)	0 (0)	1 (0.0)	.166	.460	
Blood uric acid increased	0 (0)	1 (0.0)	1 (0.0)	.331	1.000	
Body temperature increased	0 (0)	1 (0.0)	1 (0.0)	.299	1.000	
Bone pain	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Breast cancer	0 (0)	1 (0.0)	1 (0.0)	.299	1.000	
Candidiasis	1 (0.0)	0 (0)	1 (0.0)	.151	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Cardiac murmur	1 (0.0)	0 (0)	1 (0.0)	.140	.460	
Carpal tunnel decompression	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Cerebrovascular accident	1 (0.0)	0 (0)	1 (0.0)	.126	.460	
Cerumen impaction	0 (0)	1 (0.0)	1 (0.0)	.514	1.000	
Cholelithiasis	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Cold sweat	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Concussion	1 (0.0)	0 (0)	1 (0.0)	.311	.460	
Confusional state	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Costochondritis	0 (0)	1 (0.0)	1 (0.0)	.475	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Crying	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Cyst	0 (0)	1 (0.0)	1 (0.0)	.475	1.000	
Cystogram	1 (0.0)	0 (0)	1 (0.0)	.126	.460	
Cystoscopy	1 (0.0)	0 (0)	1 (0.0)	.126	.460	
Deafness	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	
Deafness bilateral	0 (0)	1 (0.0)	1 (0.0)	.290	1.000	
Dengue fever	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Dental operation	1 (0.0)	0 (0)	1 (0.0)	.372	.460	
Diabetic neuropathy	0 (0)	1 (0.0)	1 (0.0)	.482	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Dissociation	0 (0)	1 (0.0)	1 (0.0)	.432	1.000	
Dizziness postural	0 (0)	1 (0.0)	1 (0.0)	.323	1.000	
Dry skin	0 (0)	1 (0.0)	1 (0.0)	.299	1.000	
Dry throat	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	
Dysphagia	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Dysphoria	1 (0.0)	0 (0)	1 (0.0)	.475	.460	
Dyspnoea exertional	0 (0)	1 (0.0)	1 (0.0)	.315	1.000	
Eczema	1 (0.0)	0 (0)	1 (0.0)	.372	.460	
Electrocardiogram QT prolonged	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Electrocardiogram ST-T segment abnormal	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Electrocardiogram T wave abnormal	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	
Electrocardiogram abnormal	1 (0.0)	0 (0)	1 (0.0)	.333	.460	
Emotional distress	0 (0)	1 (0.0)	1 (0.0)	.514	1.000	
Endometrial cancer	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Endoscopy	1 (0.0)	0 (0)	1 (0.0)	.166	.460	
Enteritis infectious	1 (0.0)	0 (0)	1 (0.0)	.372	.460	
Erectile dysfunction	1 (0.0)	0 (0)	1 (0.0)	.356	.460	
Excoriation	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Eye discharge	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Eye disorder	1 (0.0)	0 (0)	1 (0.0)	.166	.460	
Eye infection	1 (0.0)	0 (0)	1 (0.0)	.166	.460	
Eye irritation	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Eyelid infection	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Eyelids pruritus	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Faecal incontinence	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Feeling guilty	1 (0.0)	0 (0)	1 (0.0)	.475	.460	
Feeling of despair	0 (0)	1 (0.0)	1 (0.0)	.482	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrationc/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Folliculitis	1 (0.0)	0 (0)	1 (0.0)	.333	.460	
Food craving	0 (0)	1 (0.0)	1 (0.0)	.279	1.000	
Foot fracture	0 (0)	1 (0.0)	1 (0.0)	.482	1.000	
Fracture	0 (0)	1 (0.0)	1 (0.0)	.475	1.000	
Fungal skin infection	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Gallbladder disorder	0 (0)	1 (0.0)	1 (0.0)	.310	1.000	
Gastric ulcer	0 (0)	1 (0.0)	1 (0.0)	.299	1.000	
Gastritis viral	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Gastrointestinal haemorrhage	0 (0)	1 (0.0)	1 (0.0)	.323	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Gilbert's syndrome	0 (0)	1 (0.0)	1 (0.0)	.279	1.000	
Groin pain	0 (0)	1 (0.0)	1 (0.0)	.162	1.000	
Haematoma	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Haematuria	1 (0.0)	0 (0)	1 (0.0)	.372	.460	
Haemoglobin decreased	0 (0)	1 (0.0)	1 (0.0)	.290	1.000	
Haemothorax	0 (0)	1 (0.0)	1 (0.0)	.302	1.000	
Hallucination	0 (0)	1 (0.0)	1 (0.0)	.162	1.000	
Hand fracture	0 (0)	1 (0.0)	1 (0.0)	.297	1.000	
Heart rate irregular	1 (0.0)	0 (0)	1 (0.0)	.319	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Heat exhaustion	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Hepatic function abnormal	1 (0.0)	0 (0)	1 (0.0)	.333	.460	
Hepatitis C	1 (0.0)	0 (0)	1 (0.0)	.325	.460	
Herpes zoster ophthalmic	1 (0.0)	0 (0)	1 (0.0)	.333	.460	
Hip fracture	1 (0.0)	0 (0)	1 (0.0)	.155	.460	
Hypercalcaemia	1 (0.0)	0 (0)	1 (0.0)	.372	.460	
Hypercreatinaemia	1 (0.0)	0 (0)	1 (0.0)	.329	.460	
Hyperlipidaemia	0 (0)	1 (0.0)	1 (0.0)	.475	1.000	
Hyperphagia	1 (0.0)	0 (0)	1 (0.0)	.475	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Hypersomnia	0 (0)	1 (0.0)	1 (0.0)	.514	1.000	
Hypertensive crisis	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Hypertriglyceridaemia	0 (0)	1 (0.0)	1 (0.0)	.305	1.000	
Hypocalcaemia	0 (0)	1 (0.0)	1 (0.0)	.302	1.000	
Increased tendency to bruise	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	
Increased upper airway secretion	1 (0.0)	0 (0)	1 (0.0)	.325	.460	
Infrequent bowel movements	1 (0.0)	0 (0)	1 (0.0)	.155	.460	
Intestinal ulcer	0 (0)	1 (0.0)	1 (0.0)	.297	1.000	
Intraocular lens implant	1 (0.0)	0 (0)	1 (0.0)	.140	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Irritable bowel syndrome	0 (0)	1 (0.0)	1 (0.0)	.317	1.000	
Joint sprain	1 (0.0)	0 (0)	1 (0.0)	.151	.460	
Joint stiffness	0 (0)	1 (0.0)	1 (0.0)	.297	1.000	
Laryngitis	1 (0.0)	0 (0)	1 (0.0)	.140	.460	
Ligament rupture	0 (0)	1 (0.0)	1 (0.0)	.323	1.000	
Lipid metabolism disorder	1 (0.0)	0 (0)	1 (0.0)	.333	.460	
Lithotripsy	1 (0.0)	0 (0)	1 (0.0)	.126	.460	
Liver disorder	0 (0)	1 (0.0)	1 (0.0)	.475	1.000	
Localised oedema	1 (0.0)	0 (0)	1 (0.0)	.151	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Lumbar vertebral fracture	0 (0)	1 (0.0)	1 (0.0)	.302	1.000	
Malaise	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Mania	0 (0)	1 (0.0)	1 (0.0)	.514	1.000	
Mass excision	0 (0)	1 (0.0)	1 (0.0)	.514	1.000	
Measles	1 (0.0)	0 (0)	1 (0.0)	.317	.460	
Memory impairment	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Menopause	0 (0)	1 (0.0)	1 (0.0)	.302	1.000	
Menstruation irregular	1 (0.0)	0 (0)	1 (0.0)	.335	.460	
Mole excision	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Multiple allergies	1 (0.0)	0 (0)	1 (0.0)	.475	.460	
Muscle strain	1 (0.0)	0 (0)	1 (0.0)	.356	.460	
Muscle twitching	0 (0)	1 (0.0)	1 (0.0)	.317	1.000	
Musculoskeletal stiffness	1 (0.0)	0 (0)	1 (0.0)	.166	.460	
Myocardial infarction	1 (0.0)	0 (0)	1 (0.0)	.317	.460	
Nephrolithiasis	1 (0.0)	0 (0)	1 (0.0)	.337	.460	
Nephrotic syndrome	1 (0.0)	0 (0)	1 (0.0)	.319	.460	
Nerve compression	0 (0)	1 (0.0)	1 (0.0)	.272	1.000	
Nicotine dependence	1 (0.0)	0 (0)	1 (0.0)	.475	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaeso31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Oedema	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Oesophageal ulcer	0 (0)	1 (0.0)	1 (0.0)	.299	1.000	
Ophthalmoplegia	0 (0)	1 (0.0)	1 (0.0)	.482	1.000	
Orthostatic hypotension	0 (0)	1 (0.0)	1 (0.0)	.315	1.000	
Osteitis	1 (0.0)	0 (0)	1 (0.0)	.325	.460	
Osteoporosis	1 (0.0)	0 (0)	1 (0.0)	.155	.460	
Ovarian neoplasm	1 (0.0)	0 (0)	1 (0.0)	.335	.460	
Paranasal sinus hypersecretion	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Paronychia	1 (0.0)	0 (0)	1 (0.0)	.333	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Peptic ulcer	0 (0)	1 (0.0)	1 (0.0)	.323	1.000	
Pharyngeal erythema	1 (0.0)	0 (0)	1 (0.0)	.140	.460	
Pharyngitis	1 (0.0)	0 (0)	1 (0.0)	.126	.460	
Pharyngotonsillitis	0 (0)	1 (0.0)	1 (0.0)	.514	1.000	
Piloerection	1 (0.0)	0 (0)	1 (0.0)	.317	.460	
Platelet count decreased	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Polyp	1 (0.0)	0 (0)	1 (0.0)	.166	.460	
Poor quality sleep	0 (0)	1 (0.0)	1 (0.0)	.432	1.000	
Post-traumatic pain	1 (0.0)	0 (0)	1 (0.0)	.151	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Pseudomembranous colitis	0 (0)	1 (0.0)	1 (0.0)	.514	1.000	
Rectal haemorrhage	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Renal failure	0 (0)	1 (0.0)	1 (0.0)	.323	1.000	
Respiratory disorder	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	
Restless legs syndrome	0 (0)	1 (0.0)	1 (0.0)	.279	1.000	
Rhinitis allergic	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Rhinorrhoea	1 (0.0)	0 (0)	1 (0.0)	.325	.460	
Salpingo-oophoritis	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Scapula fracture	0 (0)	1 (0.0)	1 (0.0)	.302	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Sedation	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Sensory loss	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Sinus bradycardia	0 (0)	1 (0.0)	1 (0.0)	.475	1.000	
Sinus tachycardia	1 (0.0)	0 (0)	1 (0.0)	.151	.460	
Skin irritation	0 (0)	1 (0.0)	1 (0.0)	.310	1.000	
Skin neoplasm excision	0 (0)	1 (0.0)	1 (0.0)	.498	1.000	
Sluggishness	0 (0)	1 (0.0)	1 (0.0)	.297	1.000	
Small intestine ulcer	1 (0.0)	0 (0)	1 (0.0)	.335	.460	
Social avoidant behaviour	0 (0)	1 (0.0)	1 (0.0)	.482	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Spinal fracture	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Stress urinary incontinence	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Suicidal ideation	0 (0)	1 (0.0)	1 (0.0)	.331	1.000	
Surgery	0 (0)	1 (0.0)	1 (0.0)	.272	1.000	
Synovial cyst	1 (0.0)	0 (0)	1 (0.0)	.335	.460	
Temporomandibular joint syndrome	0 (0)	1 (0.0)	1 (0.0)	.482	1.000	
Tenderness	1 (0.0)	0 (0)	1 (0.0)	.140	.460	
Therapeutic response unexpected	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Tooth disorder	0 (0)	1 (0.0)	1 (0.0)	.279	1.000	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Tooth extraction	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	
Torticollis	0 (0)	1 (0.0)	1 (0.0)	.432	1.000	
Traumatic brain injury	0 (0)	1 (0.0)	1 (0.0)	.302	1.000	
Traumatic haematoma	1 (0.0)	0 (0)	1 (0.0)	.151	.460	
Tunnel vision	0 (0)	1 (0.0)	1 (0.0)	.299	1.000	
Urethral disorder	0 (0)	1 (0.0)	1 (0.0)	.262	1.000	
Urethritis	1 (0.0)	0 (0)	1 (0.0)	.319	.460	
Urinary incontinence	0 (0)	1 (0.0)	1 (0.0)	.482	1.000	
Uterine polyp	1 (0.0)	0 (0)	1 (0.0)	.356	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Taper Discontinuation-Emergent Adverse Events
All Patients Who Entered the Drug-Tapering Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=2738) n (%)	DULOXETINE (N=3213) n (%)	TOTAL (N=5951) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Vaginitis bacterial	1 (0.0)	0 (0)	1 (0.0)	.203	.460	
Venous insufficiency	0 (0)	1 (0.0)	1 (0.0)	.486	1.000	
Ventricular extrasystoles	1 (0.0)	0 (0)	1 (0.0)	.363	.460	
Viral labyrinthitis	0 (0)	1 (0.0)	1 (0.0)	.299	1.000	
Viral upper respiratory tract infection	0 (0)	1 (0.0)	1 (0.0)	.299	1.000	
Vitreous floaters	0 (0)	1 (0.0)	1 (0.0)	.470	1.000	
Weight decreased	1 (0.0)	0 (0)	1 (0.0)	.325	.460	
White blood cell count decreased	1 (0.0)	0 (0)	1 (0.0)	.317	.460	
Wisdom teeth removal	1 (0.0)	0 (0)	1 (0.0)	.475	.460	

N = Number of patients who entered drug-tapering phase.
n = Number of patients with taper discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc3
Output: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/tfl_output/fqaesc31
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Table 3.6. Abrupt Discontinuation-Emergent Adverse Events, All Patients Who Entered the Abrupt Discontinuation Phase, All Placebo-Controlled Analyses Set, for Current Database Lock on 19 October 2011

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Patients with >= 1 Discontinuation-Emergent Adverse Event	259 (22.2)	512 (32.4)	771 (28.1)	<.001	<.001	A C
Dizziness	10 (0.9)	121 (7.6)	131 (4.8)	<.001	<.001	A B
Headache	28 (2.4)	78 (4.9)	106 (3.9)	<.001	<.001	A B
Nausea	6 (0.5)	68 (4.3)	74 (2.7)	<.001	<.001	A B
Insomnia	12 (1.0)	32 (2.0)	44 (1.6)	.059	.045	
Nasopharyngitis	16 (1.4)	24 (1.5)	40 (1.5)	.692	.872	
Diarrhoea	7 (0.6)	29 (1.8)	36 (1.3)	.002	.006	A B
Irritability	4 (0.3)	22 (1.4)	26 (0.9)	.001	.005	A B
Anxiety	6 (0.5)	19 (1.2)	25 (0.9)	.039	.069	A B

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Back pain	12 (1.0)	13 (0.8)	25 (0.9)	.964	.685	
Paraesthesia	2 (0.2)	23 (1.5)	25 (0.9)	<.001	<.001	A B
Vomiting	4 (0.3)	20 (1.3)	24 (0.9)	.009	.012	A B
Cough	11 (0.9)	10 (0.6)	21 (0.8)	.560	.381	
Fatigue	5 (0.4)	16 (1.0)	21 (0.8)	.045	.119	A B
Sinusitis	8 (0.7)	11 (0.7)	19 (0.7)	.757	1.000	
Hyperhidrosis	1 (0.1)	17 (1.1)	18 (0.7)	<.001	.001	A B
Oropharyngeal pain	8 (0.7)	9 (0.6)	17 (0.6)	.826	.807	
Influenza	7 (0.6)	9 (0.6)	16 (0.6)	.938	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Upper respiratory tract infection	6 (0.5)	10 (0.6)	16 (0.6)	.733	.803	
Asthenia	8 (0.7)	7 (0.4)	15 (0.5)	.829	.439	
Abdominal pain upper	7 (0.6)	7 (0.4)	14 (0.5)	.326	.596	
Abnormal dreams	1 (0.1)	13 (0.8)	14 (0.5)	.001	.006	A B
Arthralgia	8 (0.7)	6 (0.4)	14 (0.5)	.209	.288	
Nightmare	0 (0)	14 (0.9)	14 (0.5)	<.001	<.001	A
Vertigo	0 (0)	14 (0.9)	14 (0.5)	<.001	<.001	A
Dyspepsia	4 (0.3)	9 (0.6)	13 (0.5)	.190	.576	
Dry mouth	4 (0.3)	8 (0.5)	12 (0.4)	.458	.575	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Myalgia	2 (0.2)	10 (0.6)	12 (0.4)	.062	.083	B
Tinnitus	2 (0.2)	10 (0.6)	12 (0.4)	.069	.083	B
Abdominal pain	7 (0.6)	4 (0.3)	11 (0.4)	.284	.221	
Bronchitis	3 (0.3)	8 (0.5)	11 (0.4)	.341	.373	
Muscle spasms	7 (0.6)	4 (0.3)	11 (0.4)	.238	.221	
Urinary tract infection	5 (0.4)	6 (0.4)	11 (0.4)	.740	1.000	
Abdominal discomfort	4 (0.3)	6 (0.4)	10 (0.4)	.692	1.000	
Constipation	4 (0.3)	6 (0.4)	10 (0.4)	.920	1.000	
Flatulence	2 (0.2)	8 (0.5)	10 (0.4)	.129	.206	B

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Somnolence	1 (0.1)	9 (0.6)	10 (0.4)	.027	.051	A B
Decreased appetite	2 (0.2)	6 (0.4)	8 (0.3)	.391	.480	B
Weight increased	2 (0.2)	6 (0.4)	8 (0.3)	.353	.480	B
Disturbance in attention	3 (0.3)	4 (0.3)	7 (0.3)	.737	1.000	
Increased appetite	1 (0.1)	6 (0.4)	7 (0.3)	.130	.250	B
Influenza like illness	2 (0.2)	5 (0.3)	7 (0.3)	.379	.706	
Neck pain	2 (0.2)	5 (0.3)	7 (0.3)	.423	.706	
Pain	3 (0.3)	4 (0.3)	7 (0.3)	.749	1.000	
Palpitations	1 (0.1)	6 (0.4)	7 (0.3)	.168	.250	B

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Pruritus	1 (0.1)	6 (0.4)	7 (0.3)	.062	.250	B
Pyrexia	0 (0)	7 (0.4)	7 (0.3)	.014	.023	A
Viral upper respiratory tract infection	3 (0.3)	4 (0.3)	7 (0.3)	.665	1.000	
Crying	1 (0.1)	5 (0.3)	6 (0.2)	.142	.250	B
Gastroenteritis viral	3 (0.3)	3 (0.2)	6 (0.2)	.990	.703	
Libido increased	0 (0)	6 (0.4)	6 (0.2)	.015	.042	A
Nasal congestion	3 (0.3)	3 (0.2)	6 (0.2)	.498	.703	
Rhinitis	1 (0.1)	5 (0.3)	6 (0.2)	.185	.250	B
Seasonal allergy	2 (0.2)	4 (0.3)	6 (0.2)	.560	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Sinus congestion	2 (0.2)	4 (0.3)	6 (0.2)	.767	1.000	
Tearfulness	3 (0.3)	3 (0.2)	6 (0.2)	.975	.703	
Tension headache	0 (0)	6 (0.4)	6 (0.2)	.054	.042	
Vision blurred	2 (0.2)	4 (0.3)	6 (0.2)	.538	1.000	
Abdominal distension	0 (0)	5 (0.3)	5 (0.2)	.045	.077	A
Balance disorder	0 (0)	5 (0.3)	5 (0.2)	.038	.077	A
Chills	2 (0.2)	3 (0.2)	5 (0.2)	.866	1.000	
Depression	0 (0)	5 (0.3)	5 (0.2)	.060	.077	
Dysmenorrhoea	3 (0.3)	2 (0.1)	5 (0.2)	.376	.656	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Dyspnoea	1 (0.1)	4 (0.3)	5 (0.2)	.363	.403	B
Hot flush	1 (0.1)	4 (0.3)	5 (0.2)	.205	.403	B
Hypertension	1 (0.1)	4 (0.3)	5 (0.2)	.256	.403	B
Hypoaesthesia	1 (0.1)	4 (0.3)	5 (0.2)	.209	.403	B
Musculoskeletal pain	2 (0.2)	3 (0.2)	5 (0.2)	.494	1.000	
Nervousness	3 (0.3)	2 (0.1)	5 (0.2)	.594	.656	
Tachycardia	0 (0)	5 (0.3)	5 (0.2)	.018	.077	A
Tension	1 (0.1)	4 (0.3)	5 (0.2)	.373	.403	B
Tremor	1 (0.1)	4 (0.3)	5 (0.2)	.265	.403	B

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Chest discomfort	2 (0.2)	2 (0.1)	4 (0.1)	.926	1.000	
Chest pain	3 (0.3)	1 (0.1)	4 (0.1)	.332	.318	
Cystitis	3 (0.3)	1 (0.1)	4 (0.1)	.208	.318	
Depressed mood	2 (0.2)	2 (0.1)	4 (0.1)	.794	1.000	
Ear infection	4 (0.3)	0 (0)	4 (0.1)	.034	.032	
Erectile dysfunction	1 (0.1)	3 (0.2)	4 (0.1)	.683	.642	B
Labyrinthitis	0 (0)	4 (0.3)	4 (0.1)	.062	.142	
Libido decreased	1 (0.1)	3 (0.2)	4 (0.1)	.422	.642	B
Localised infection	1 (0.1)	3 (0.2)	4 (0.1)	.396	.642	B

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Middle insomnia	0 (0)	4 (0.3)	4 (0.1)	.095	.142	
Migraine	1 (0.1)	3 (0.2)	4 (0.1)	.310	.642	B
Oedema peripheral	1 (0.1)	3 (0.2)	4 (0.1)	.430	.642	B
Pneumonia	4 (0.3)	0 (0)	4 (0.1)	.004	.032	
Pollakiuria	3 (0.3)	1 (0.1)	4 (0.1)	.241	.318	
Rash	0 (0)	4 (0.3)	4 (0.1)	.167	.142	
Rhinorrhoea	1 (0.1)	3 (0.2)	4 (0.1)	.470	.642	B
Sleep disorder	1 (0.1)	3 (0.2)	4 (0.1)	.486	.642	B
Affect lability	0 (0)	3 (0.2)	3 (0.1)	.126	.267	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Anger	0 (0)	3 (0.2)	3 (0.1)	.172	.267	
Arthritis	1 (0.1)	2 (0.1)	3 (0.1)	.388	1.000	
Blood pressure increased	0 (0)	3 (0.2)	3 (0.1)	.092	.267	
Energy increased	1 (0.1)	2 (0.1)	3 (0.1)	.573	1.000	
Fluid retention	1 (0.1)	2 (0.1)	3 (0.1)	.759	1.000	
Food poisoning	1 (0.1)	2 (0.1)	3 (0.1)	.984	1.000	
Gastritis	2 (0.2)	1 (0.1)	3 (0.1)	.353	.578	
Heart rate increased	0 (0)	3 (0.2)	3 (0.1)	.156	.267	
Initial insomnia	1 (0.1)	2 (0.1)	3 (0.1)	.774	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Laceration	2 (0.2)	1 (0.1)	3 (0.1)	.613	.578	
Muscular weakness	0 (0)	3 (0.2)	3 (0.1)	.094	.267	
Pain in extremity	0 (0)	3 (0.2)	3 (0.1)	.066	.267	
Procedural pain	1 (0.1)	2 (0.1)	3 (0.1)	.786	1.000	
Restlessness	2 (0.2)	1 (0.1)	3 (0.1)	.548	.578	
Rhinitis allergic	1 (0.1)	2 (0.1)	3 (0.1)	.628	1.000	
Upper-airway cough syndrome	2 (0.2)	1 (0.1)	3 (0.1)	.579	.578	
Urticaria	2 (0.2)	1 (0.1)	3 (0.1)	.410	.578	
Weight decreased	1 (0.1)	2 (0.1)	3 (0.1)	.661	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Accidental overdose	0 (0)	2 (0.1)	2 (0.1)	.134	.511	
Agitation	0 (0)	2 (0.1)	2 (0.1)	.149	.511	
Akathisia	0 (0)	2 (0.1)	2 (0.1)	.229	.511	
Anhedonia	2 (0.2)	0 (0)	2 (0.1)	.187	.180	
Blood bilirubin increased	0 (0)	2 (0.1)	2 (0.1)	.422	.511	
Blood creatine phosphokinase increased	2 (0.2)	0 (0)	2 (0.1)	.092	.180	
Bursitis	1 (0.1)	1 (0.1)	2 (0.1)	.622	1.000	
Colonic polyp	1 (0.1)	1 (0.1)	2 (0.1)	.750	1.000	
Colonoscopy	1 (0.1)	1 (0.1)	2 (0.1)	.948	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integraticns/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Conjunctivitis	0 (0)	2 (0.1)	2 (0.1)	.226	.511	
Contusion	1 (0.1)	1 (0.1)	2 (0.1)	.976	1.000	
Dental caries	2 (0.2)	0 (0)	2 (0.1)	.045	.180	
Depersonalisation	0 (0)	2 (0.1)	2 (0.1)	.231	.511	
Derealisation	0 (0)	2 (0.1)	2 (0.1)	.237	.511	
Dry eye	0 (0)	2 (0.1)	2 (0.1)	.190	.511	
Dry skin	0 (0)	2 (0.1)	2 (0.1)	.190	.511	
Dysgeusia	0 (0)	2 (0.1)	2 (0.1)	.191	.511	
Endoscopy	1 (0.1)	1 (0.1)	2 (0.1)	.948	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Fall	0 (0)	2 (0.1)	2 (0.1)	.167	.511	
Feeling abnormal	0 (0)	2 (0.1)	2 (0.1)	.162	.511	
Feeling guilty	2 (0.2)	0 (0)	2 (0.1)	.270	.180	
Feeling jittery	1 (0.1)	1 (0.1)	2 (0.1)	.937	1.000	
Feeling of despair	1 (0.1)	1 (0.1)	2 (0.1)	.843	1.000	
Fibromyalgia	0 (0)	2 (0.1)	2 (0.1)	.249	.511	
Frequent bowel movements	0 (0)	2 (0.1)	2 (0.1)	.325	.511	
Gastroenteritis	1 (0.1)	1 (0.1)	2 (0.1)	.818	1.000	
Hypersensitivity	2 (0.2)	0 (0)	2 (0.1)	.172	.180	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Hypersomnia	1 (0.1)	1 (0.1)	2 (0.1)	.798	1.000	
Hypothyroidism	0 (0)	2 (0.1)	2 (0.1)	.380	.511	
Increased bronchial secretion	2 (0.2)	0 (0)	2 (0.1)	.171	.180	
Joint sprain	1 (0.1)	1 (0.1)	2 (0.1)	.818	1.000	
Joint stiffness	0 (0)	2 (0.1)	2 (0.1)	.212	.511	
Laryngitis	0 (0)	2 (0.1)	2 (0.1)	.186	.511	
Mitral valve prolapse	0 (0)	2 (0.1)	2 (0.1)	.212	.511	
Muscle injury	1 (0.1)	1 (0.1)	2 (0.1)	.990	1.000	
Muscle strain	2 (0.2)	0 (0)	2 (0.1)	.092	.180	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Muscle twitching	0 (0)	2 (0.1)	2 (0.1)	.212	.511	
Musculoskeletal stiffness	0 (0)	2 (0.1)	2 (0.1)	.191	.511	
Night sweats	0 (0)	2 (0.1)	2 (0.1)	.259	.511	
Orthostatic hypotension	1 (0.1)	1 (0.1)	2 (0.1)	.960	1.000	
Panic attack	0 (0)	2 (0.1)	2 (0.1)	.070	.511	
Pharyngitis streptococcal	1 (0.1)	1 (0.1)	2 (0.1)	.726	1.000	
Sedation	0 (0)	2 (0.1)	2 (0.1)	.158	.511	
Sinus bradycardia	1 (0.1)	1 (0.1)	2 (0.1)	.514	1.000	
Sluggishness	1 (0.1)	1 (0.1)	2 (0.1)	.919	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Surgery	2 (0.2)	0 (0)	2 (0.1)	.188	.180	
Tendonitis	1 (0.1)	1 (0.1)	2 (0.1)	.818	1.000	
Urine analysis abnormal	0 (0)	2 (0.1)	2 (0.1)	.155	.511	
Viral infection	2 (0.2)	0 (0)	2 (0.1)	.050	.180	
Acute sinusitis	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	
Aggression	1 (0.1)	0 (0)	1 (0.0)	.352	.424	
Alanine aminotransferase increased	1 (0.1)	0 (0)	1 (0.0)	.077	.424	
Allergic sinusitis	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	
Amnesia	0 (0)	1 (0.1)	1 (0.0)	.472	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Anaemia	1 (0.1)	0 (0)	1 (0.0)	.335	.424	
Apathy	1 (0.1)	0 (0)	1 (0.0)	.352	.424	
Aphonia	1 (0.1)	0 (0)	1 (0.0)	.255	.424	
Arthropod bite	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	
Arthropod sting	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Asthma	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Axillary pain	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Bacterial infection	1 (0.1)	0 (0)	1 (0.0)	.317	.424	
Bacteriuria	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Benign colonic neoplasm	1 (0.1)	0 (0)	1 (0.0)	.169	.424	
Biliary colic	0 (0)	1 (0.1)	1 (0.0)	.472	1.000	
Binge eating	0 (0)	1 (0.1)	1 (0.0)	.104	1.000	
Biopsy endometrium	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Blepharospasm	1 (0.1)	0 (0)	1 (0.0)	.255	.424	
Blood cholesterol increased	0 (0)	1 (0.1)	1 (0.0)	.617	1.000	
Blood pressure decreased	1 (0.1)	0 (0)	1 (0.0)	.317	.424	
Bone density decreased	1 (0.1)	0 (0)	1 (0.0)	.352	.424	
Bone pain	1 (0.1)	0 (0)	1 (0.0)	.164	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Breast cancer	0 (0)	1 (0.1)	1 (0.0)	.283	1.000	
Bronchitis chronic	1 (0.1)	0 (0)	1 (0.0)	.385	.424	
Candidiasis	1 (0.1)	0 (0)	1 (0.0)	.313	.424	
Cardio-respiratory arrest	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Carpal tunnel syndrome	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Cervical cyst	1 (0.1)	0 (0)	1 (0.0)	.162	.424	
Cervical dysplasia	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Cervical polyp	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Cervicitis	0 (0)	1 (0.1)	1 (0.0)	.264	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Cholelithiasis	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Clavicle fracture	0 (0)	1 (0.1)	1 (0.0)	.572	1.000	
Cluster headache	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	
Concussion	1 (0.1)	0 (0)	1 (0.0)	.335	.424	
Conversion disorder	0 (0)	1 (0.1)	1 (0.0)	.572	1.000	
Coordination abnormal	0 (0)	1 (0.1)	1 (0.0)	.331	1.000	
Corneal disorder	1 (0.1)	0 (0)	1 (0.0)	.371	.424	
Decreased activity	1 (0.1)	0 (0)	1 (0.0)	.352	.424	
Decreased interest	1 (0.1)	0 (0)	1 (0.0)	.352	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Disorientation	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	
Disturbance in sexual arousal	1 (0.1)	0 (0)	1 (0.0)	.162	.424	
Dry throat	0 (0)	1 (0.1)	1 (0.0)	.264	1.000	
Dysaesthesia	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	
Dysarthria	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	
Dysphonia	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	
Dysphoria	1 (0.1)	0 (0)	1 (0.0)	.539	.424	
Dysuria	1 (0.1)	0 (0)	1 (0.0)	.317	.424	
Ear pain	1 (0.1)	0 (0)	1 (0.0)	.539	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Ejaculation disorder	0 (0)	1 (0.1)	1 (0.0)	.617	1.000	
Electrocardiogram T wave abnormal	0 (0)	1 (0.1)	1 (0.0)	.573	1.000	
Emotional disorder	0 (0)	1 (0.1)	1 (0.0)	.572	1.000	
Emphysema	1 (0.1)	0 (0)	1 (0.0)	.335	.424	
Endometrial disorder	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Enteritis	1 (0.1)	0 (0)	1 (0.0)	.164	.424	
Erysipelas	0 (0)	1 (0.1)	1 (0.0)	.572	1.000	
Euphoric mood	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	
Exostosis	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillycc/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Eye irritation	1 (0.1)	0 (0)	1 (0.0)	.303	.424	
Eye operation	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Eye pruritus	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Facial paresis	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Feeling hot	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Feeling of body temperature change	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	
Flushing	0 (0)	1 (0.1)	1 (0.0)	.283	1.000	
Food craving	0 (0)	1 (0.1)	1 (0.0)	.283	1.000	
Formication	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Full blood count abnormal	1 (0.1)	0 (0)	1 (0.0)	.317	.424	
Fungal infection	1 (0.1)	0 (0)	1 (0.0)	.303	.424	
Fungal skin infection	0 (0)	1 (0.1)	1 (0.0)	.617	1.000	
Gamma-glutamyltransferase increased	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Gastric ulcer	0 (0)	1 (0.1)	1 (0.0)	.472	1.000	
Gastrointestinal pain	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	
Gilbert's syndrome	0 (0)	1 (0.1)	1 (0.0)	.572	1.000	
Gout	1 (0.1)	0 (0)	1 (0.0)	.385	.424	
Haematoma	0 (0)	1 (0.1)	1 (0.0)	.472	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Haematuria	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Haemorrhoids	1 (0.1)	0 (0)	1 (0.0)	.169	.424	
Head discomfort	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Hepatic enzyme increased	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	
Herpes zoster	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Hypercholesterolaemia	1 (0.1)	0 (0)	1 (0.0)	.313	.424	
Hyperlipidaemia	1 (0.1)	0 (0)	1 (0.0)	.385	.424	
Hyperphagia	1 (0.1)	0 (0)	1 (0.0)	.539	.424	
Hyperprolactinaemia	0 (0)	1 (0.1)	1 (0.0)	.572	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Hypertonia	1 (0.1)	0 (0)	1 (0.0)	.539	.424	
Hypertriglyceridaemia	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Hyperventilation	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Hypoaesthesia oral	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Hypomania	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Impatience	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Incontinence	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Infection	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	
Irritable bowel syndrome	1 (0.1)	0 (0)	1 (0.0)	.317	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Joint injury	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Lacrimation increased	1 (0.1)	0 (0)	1 (0.0)	.317	.424	
Leukopenia	0 (0)	1 (0.1)	1 (0.0)	.283	1.000	
Limb injury	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	
Lipoma	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Localised oedema	1 (0.1)	0 (0)	1 (0.0)	.313	.424	
Lymphocyte count increased	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Malaise	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Measles	1 (0.1)	0 (0)	1 (0.0)	.319	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Melanocytic naevus	0 (0)	1 (0.1)	1 (0.0)	.331	1.000	
Menorrhagia	1 (0.1)	0 (0)	1 (0.0)	.303	.424	
Menstrual disorder	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Menstruation irregular	1 (0.1)	0 (0)	1 (0.0)	.169	.424	
Metrorrhagia	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Miosis	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Mitral valve incompetence	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	
Mood altered	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Morbid thoughts	1 (0.1)	0 (0)	1 (0.0)	.352	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Multiple allergies	1 (0.1)	0 (0)	1 (0.0)	.539	.424	
Muscle operation	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	
Muscle tightness	0 (0)	1 (0.1)	1 (0.0)	.331	1.000	
Myocardial infarction	1 (0.1)	0 (0)	1 (0.0)	.319	.424	
Myocardial ischaemia	0 (0)	1 (0.1)	1 (0.0)	.573	1.000	
Myopia	1 (0.1)	0 (0)	1 (0.0)	.371	.424	
Nasal dryness	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Neuropathy peripheral	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Neurosis	1 (0.1)	0 (0)	1 (0.0)	.385	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Neutrophil count increased	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Nicotine dependence	1 (0.1)	0 (0)	1 (0.0)	.539	.424	
Onychoclasis	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Onychomycosis	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Oral dysaesthesia	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	
Oral infection	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Oral pain	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Orgasm abnormal	0 (0)	1 (0.1)	1 (0.0)	.617	1.000	
Osteoarthritis	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Otitis externa	1 (0.1)	0 (0)	1 (0.0)	.371	.424	
Ovarian neoplasm	1 (0.1)	0 (0)	1 (0.0)	.169	.424	
Pain in jaw	1 (0.1)	0 (0)	1 (0.0)	.317	.424	
Pelvic pain	1 (0.1)	0 (0)	1 (0.0)	.335	.424	
Penile pain	1 (0.1)	0 (0)	1 (0.0)	.371	.424	
Pharyngitis	1 (0.1)	0 (0)	1 (0.0)	.162	.424	
Phonological disorder	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Photosensitivity reaction	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Piloerection	1 (0.1)	0 (0)	1 (0.0)	.319	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Platelet count decreased	0 (0)	1 (0.1)	1 (0.0)	.573	1.000	
Post procedural infection	0 (0)	1 (0.1)	1 (0.0)	.617	1.000	
Post-traumatic pain	1 (0.1)	0 (0)	1 (0.0)	.313	.424	
Postmenopausal haemorrhage	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Postoperative wound complication	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Pregnancy	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	
Premenstrual syndrome	1 (0.1)	0 (0)	1 (0.0)	.335	.424	
Presbyopia	1 (0.1)	0 (0)	1 (0.0)	.046	.424	
Prostatic disorder	1 (0.1)	0 (0)	1 (0.0)	.371	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Psychomotor retardation	0 (0)	1 (0.1)	1 (0.0)	.104	1.000	
Rash pruritic	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Rectal prolapse	1 (0.1)	0 (0)	1 (0.0)	.303	.424	
Removal of internal fixation	0 (0)	1 (0.1)	1 (0.0)	.250	1.000	
Renal disorder	1 (0.1)	0 (0)	1 (0.0)	.385	.424	
Renal impairment	1 (0.1)	0 (0)	1 (0.0)	.385	.424	
Renal pain	0 (0)	1 (0.1)	1 (0.0)	.573	1.000	
Respiratory disorder	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	
Respiratory tract congestion	1 (0.1)	0 (0)	1 (0.0)	.303	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Retinal aneurysm	0 (0)	1 (0.1)	1 (0.0)	.264	1.000	
Road traffic accident	1 (0.1)	0 (0)	1 (0.0)	.169	.424	
Sensation of heaviness	0 (0)	1 (0.1)	1 (0.0)	.283	1.000	
Sinus headache	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	
Sinus tachycardia	1 (0.1)	0 (0)	1 (0.0)	.313	.424	
Sleep talking	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	
Small intestine ulcer	1 (0.1)	0 (0)	1 (0.0)	.169	.424	
Smear cervix abnormal	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	
Sneezing	1 (0.1)	0 (0)	1 (0.0)	.150	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaeso41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Spinal osteoarthritis	0 (0)	1 (0.1)	1 (0.0)	.472	1.000	
Suicidal ideation	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Supraventricular extrasystoles	0 (0)	1 (0.1)	1 (0.0)	.472	1.000	
Syncope	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Synovial cyst	1 (0.1)	0 (0)	1 (0.0)	.169	.424	
Synovitis	0 (0)	1 (0.1)	1 (0.0)	.472	1.000	
Tendon injury	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Thinking abnormal	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Thirst	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Throat irritation	1 (0.1)	0 (0)	1 (0.0)	.335	.424	
Tinea infection	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	
Tooth abscess	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Tooth extraction	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
Tooth fracture	0 (0)	1 (0.1)	1 (0.0)	.315	1.000	
Tooth loss	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Toothache	0 (0)	1 (0.1)	1 (0.0)	.331	1.000	
Traumatic haematoma	1 (0.1)	0 (0)	1 (0.0)	.313	.424	
Tricuspid valve incompetence	0 (0)	1 (0.1)	1 (0.0)	.300	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Trigeminal neuralgia	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Upper respiratory tract inflammation	1 (0.1)	0 (0)	1 (0.0)	.162	.424	
Urinary hesitation	1 (0.1)	0 (0)	1 (0.0)	.317	.424	
Urinary incontinence	0 (0)	1 (0.1)	1 (0.0)	.474	1.000	
Uterine dilation and curettage	1 (0.1)	0 (0)	1 (0.0)	.255	.424	
Vaginal discharge	0 (0)	1 (0.1)	1 (0.0)	.322	1.000	
Vaginal haemorrhage	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Vaginal infection	1 (0.1)	0 (0)	1 (0.0)	.352	.424	
Vaginitis bacterial	0 (0)	1 (0.1)	1 (0.0)	.380	1.000	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads

Abrupt Discontinuation-Emergent Adverse Events
All Patients Who Entered the Abrupt Discontinuation Phase
All Placebo-Controlled Analyses Set

MedDRA Preferred Term	PLACEBO (N=1166) n (%)	DULOXETINE (N=1582) n (%)	TOTAL (N=2748) n (%)	CMH p-Value (a)	Fisher's Exact p-Value (b)	CRITERIA
Vertigo positional	0 (0)	1 (0.1)	1 (0.0)	.283	1.000	
Vulvovaginal discomfort	1 (0.1)	0 (0)	1 (0.0)	.076	.424	
Vulvovaginal mycotic infection	1 (0.1)	0 (0)	1 (0.0)	.352	.424	
Vulvovaginal pruritus	0 (0)	1 (0.1)	1 (0.0)	.467	1.000	
Whiplash injury	0 (0)	1 (0.1)	1 (0.0)	.264	1.000	
White blood cell count decreased	1 (0.1)	0 (0)	1 (0.0)	.319	.424	
White blood cell count increased	0 (0)	1 (0.1)	1 (0.0)	.488	1.000	
White blood cells urine positive	0 (0)	1 (0.1)	1 (0.0)	.317	1.000	
Wisdom teeth removal	1 (0.1)	0 (0)	1 (0.0)	.539	.424	

N = Number of patients who entered abrupt discontinuation phase.
n = Number of patients with abrupt discontinuation-emergent adverse event.
baseline: VISSTD 1-199 (used patients last two visits), postbaseline: VISSTD 700-799

(a) Frequencies are analyzed using Cochran-Mantel-Haenszel test for general association controlling for study.
(b) Fisher's Exact Test.

MedDRA Version: 14.0
Criterion A: Adverse event rate higher in Duloxetine group than in Placebo group and CMH P-value < 0.05.
Criterion B: Adverse event rate in Duloxetine group is twice that of Placebo group and rate in Placebo group greater than zero.
Criterion C: Adverse event rate in Duloxetine group is greater than or equal to 10 percent.

Program: home/lillyce/prd/ly248686/integrations/pedss_adult/programs_stat/fqaesc4
Output: home/prd/ly248686/integrations/pedss_adult/program_stat/fqaesc41.rtf
Data: home/lillyce/prd/ly248686/integrations/q311sidb/data/ads