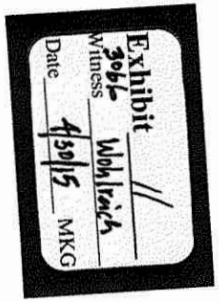
Skin odour abnormal	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.307
Social problem	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Speech disorder	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.307
Subcutaneous abscess	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.317
Tachyarrhythmia	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Tearfulness	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.307
Tendon disorder	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.327
Thermal burn	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.327
Throat tightness	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.317
Tinea infection	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Tongue biting	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.327
Tonsillitis	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Tooth disorder	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Torticollis	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.317
Trismus	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Umbilical hernia	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.317
Urge incontinence	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Urinary retention	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.307
Urinary tract disorder	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Uterine infection	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.307
Vaginal candidiasis	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Vaginal mycosis	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.327
Vaginal odour	1(0.3%)	0(0.0%)	1(0.1%)	0.495	0.317
Varicose vein operation	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Viral upper respiratory tract infection	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317
Visual disturbance	0(0.0%)	1(0.3%)	1(0.1%)	1.000	0.317

MedDRA version: 8.0
Baseline visits: 1-3, Postbaseline visits: 4-10
CMH = Cochran-Mantel-Haenszel test for general association, controlling for study.
Program: RMP.F1JSHMCQ.SASPGM(FQTAEG1B)
Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL & RMP.SAS.F1JM.L.MCHMCQSW.FINAL

Table 4.138. Treatment-Emergent Adverse Events - MedDRA Preferred Terms By Decreasing Frequency All Patients who Entered Study Period IV F1J-MC-HMBU & HMCQ Study Period IV

Event	Dulox (N=195) n(%)	Venlafax (N=328) n(%)	Total (N=523) n(%)	Fishers Exact p-value	CMH p-value



PATIENTS WITH >=1 TESS	87(44.6%)	181(55.2%)	268(51.2%)	0.024	0.159
Dizziness	27(13.8%)	81(24.7%)	108(20.7%)	0.004	0.016
Headache	10(5.1%)	31(9.5%)	41(7.8%)	0.092	0.162
Nausea	9(4.6%)	29(8.8%)	38(7.3%)	0.082	0.120
Insomnia	5(2.6%)	25(7.6%)	30(5.7%)	0.019	0.014
Diarrhoea	7(3.6%)	21(6.4%)	28(5.4%)	0.228	0.157
Irritability	7(3.6%)	20(6.1%)	27(5.2%)	0.229	0.383
Vomiting	2(1.0%)	16(4.9%)	18(3.4%)	0.023	0.035
Abnormal dreams	7(3.6%)	10(3.0%)	17(3.3%)	0.801	0.672
Hyperhidrosis	4(2.1%)	12(3.7%)	16(3.1%)	0.432	0.356
Anxiety	2(1.0%)	12(3.7%)	14(2.7%)	0.093	0.089
Fatigue	1(0.5%)	13(4.0%)	14(2.7%)	0.022	0.014
Nightmare	3(1.5%)	9(2.7%)	12(2.3%)	0.549	0.459
Paraesthesia	2(1.0%)	10(3.0%)	12(2.3%)	0.226	0.173
Tearfulness	1(0.5%)	9(2.7%)	10(1.9%)	0.099	0.121
Upper respiratory tract infection	4(2.1%)	6(1.8%)	10(1.9%)	1.000	0.599
Back pain	2(1.0%)	7(2.1%)	9(1.7%)	0.495	0.235
Influenza	4(2.1%)	5(1.5%)	9(1.7%)	0.733	0.447
Decreased appetite	0(0.0%)	8(2.4%)	8(1.5%)	0.028	0.041
Hot flush	2(1.0%)	6(1.8%)	8(1.5%)	0.716	0.709
Somnolence	4(2.1%)	4(1.2%)	8(1.5%)	0.479	0.476
Stomach discomfort	3(1.5%)	5(1.5%)	8(1.5%)	1.000	0.973
Vision blurred	4(2.1%)	4(1.2%)	8(1.5%)	0.479	0.476
Abdominal pain	3(1.5%)	4(1.2%)	7(1.3%)	0.715	0.848
Asthenia	1(0.5%)	6(1.8%)	7(1.3%)	0.266	0.323
Palpitations	3(1.5%)	4(1.2%)	7(1.3%)	0.715	0.730
Tinnitus	2(1.0%)	5(1.5%)	7(1.3%)	1.000	0.756

MedDRA version: 7.0
Baseline visits: 1-10, Postbaseline visits: 301-303
CMH = Cochran-Mantel-Haenszel test for general association, controlling for study.
Program: RMP.F1JSHMCQ.SASPGM(FQTAEG1C)
Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL & RMP.SAS.F1JM.L.MCHMCQSW.FINAL

Treatment-Emergent Adverse Events - MedDRA Preferred Terms
By Decreasing Frequency
All Patients who Entered Study Period IV
F1J-MC-HMBU & HMCQ Study Period IV

Event	Dulox (N=195) n(%)	Venlafax (N=328) n(%)	Total (N=523) n(%)	Fishers Exact p-value	CMH p-value
Nasopharyngitis	4(2.1%)	2(0.6%)	6(1.1%)	0.202	0.095

Pyrexia	1(0.5%)	5(1.5%)	6(1.1%)	0.419	0.338
Constipation	0(0.0%)	5(1.5%)	5(1.0%)	0.163	0.115
Cough	1(0.5%)	4(1.2%)	5(1.0%)	0.655	0.547
Disorientation	1(0.5%)	4(1.2%)	5(1.0%)	0.655	0.667
Loose stools	1(0.5%)	4(1.2%)	5(1.0%)	0.655	0.547
Myalgia	1(0.5%)	4(1.2%)	5(1.0%)	0.655	0.442
Pharyngolaryngeal pain	0(0.0%)	5(1.5%)	5(1.0%)	0.163	0.154
Sinus congestion	1(0.5%)	4(1.2%)	5(1.0%)	0.655	0.667
Sinusitis	3(1.5%)	2(0.6%)	5(1.0%)	0.367	0.180
Vertigo	1(0.5%)	4(1.2%)	5(1.0%)	0.655	0.667
Initial insomnia	2(1.0%)	2(0.6%)	4(0.8%)	0.631	0.472
Middle insomnia	0(0.0%)	4(1.2%)	4(0.8%)	0.302	0.203
Pruritus	1(0.5%)	3(0.9%)	4(0.8%)	1.000	0.719
Rigors	0(0.0%)	4(1.2%)	4(0.8%)	0.302	0.150
Blood pressure increased	1(0.5%)	2(0.6%)	3(0.6%)	1.000	0.778
Chest pain	1(0.5%)	2(0.6%)	3(0.6%)	1.000	0.778
Erythema	2(1.0%)	1(0.3%)	3(0.6%)	0.559	0.504
Flatulence	2(1.0%)	1(0.3%)	3(0.6%)	0.559	0.362
Increased appetite	0(0.0%)	3(0.9%)	3(0.6%)	0.297	0.271
Night sweats	1(0.5%)	2(0.6%)	3(0.6%)	1.000	0.953
Pain in extremity	0(0.0%)	3(0.9%)	3(0.6%)	0.297	0.098
Sensation of heaviness	2(1.0%)	1(0.3%)	3(0.6%)	0.559	0.362
Sleep disorder	1(0.5%)	2(0.6%)	3(0.6%)	1.000	0.622
Tremor	2(1.0%)	1(0.3%)	3(0.6%)	0.559	0.362
Abdominal pain upper	2(1.0%)	0(0.0%)	2(0.4%)	0.139	0.066
Affect lability	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.178

MedDRA version: 7.0
Baseline visits: 1-10, Postbaseline visits: 301-303
CMH = Cochran-Mantel-Haenszel test for general association, controlling for study.
Program: RMP.F1JSHMCQ.SASPGM(FQTAEG1C)
Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL & RMP.SAS.F1JM.L.MCHMCQSW.FINAL

Treatment-Emergent Adverse Events - MedDRA Preferred Terms
By Decreasing Frequency
All Patients who Entered Study Period IV
F1J-MC-HMBU & HMCQ Study Period IV

Event	Dulox (N=195) n(%)	Venlafax (N=328) n(%)	Total (N=523) n(%)	Fishers Exact p-value	CMH p-value
Apathy	1(0.5%)	1(0.3%)	2(0.4%)	1.000	0.503
Crying	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.370

Disturbance in attention	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.258
Dry mouth	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.258
Dyspnoea	2(1.0%)	0(0.0%)	2(0.4%)	0.139	0.066
Ear pain	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.258
Feeling hot and cold	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.370
Gastroenteritis	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.370
Lethargy	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.258
Migraine	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.370
Nasal congestion	1(0.5%)	1(0.3%)	2(0.4%)	1.000	0.503
Rash	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.370
Rhinorrhoea	1(0.5%)	1(0.3%)	2(0.4%)	1.000	0.503
Sinus pain	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.258
Sneezing	0(0.0%)	2(0.6%)	2(0.4%)	0.531	0.370
Suicidal ideation	1(0.5%)	1(0.3%)	2(0.4%)	1.000	0.723
Thirst	1(0.5%)	1(0.3%)	2(0.4%)	1.000	0.503
Toothache	2(1.0%)	0(0.0%)	2(0.4%)	0.139	0.025
Urinary incontinence	1(0.5%)	1(0.3%)	2(0.4%)	1.000	0.503
Abdominal discomfort	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Abscess	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Acrochordon excision	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Agitation	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Akathisia	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Alanine aminotransferase increased	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Anger	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Aphonia	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114

MedDRA version: 7.0
Baseline visits: 1-10, Postbaseline visits: 301-303
CMH = Cochran-Mantel-Haenszel test for general association, controlling for study.
Program: RMP.F1JSHMCQ.SASPGM(FQTAEG1C)
Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL & RMP.SAS.F1JM.L.MCHMCQSW.FINAL

Treatment-Emergent Adverse Events - MedDRA Preferred Terms
By Decreasing Frequency
All Patients who Entered Study Period IV
F1J-MC-HMBU & HMCQ Study Period IV

Event	Dulox (N=195) n(%)	Venlafax (N=328) n(%)	Total (N=523) n(%)	Fishers Exact p-value	CMH p-value
Arthralgia	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Arthritis	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Aspartate aminotransferase increased	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527

Ataxia	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Balance disorder	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Blood pressure decreased	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Blood prolactin increased	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Breast tenderness	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Bronchitis	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Bruxism	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Bundle branch block	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Central nervous system stimulation	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Cerumen impaction	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Chest discomfort	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Confusional state	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Deafness unilateral	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Defaecation urgency	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Dehydration	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Depression	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Diarrhoea infectious	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Distractibility	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Dry skin	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Electrocardiogram T wave abnormal	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Emotional disorder	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Eye pain	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Eye pruritus	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Fear	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527

MedDRA version: 7.0
Baseline visits: 1-10, Postbaseline visits: 301-303
CMH = Coohran-Mantel-Haenszel test for general association, controlling for study.
Program: RMP.F1JSHMCQ.SASPGM(FQTAEG1C)
Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL & RMP.SAS.F1JM.L.MCHMCQSW.FINAL
1PRODUCTION DATA - PRODUCTION MODE

Treatment-Emergent Adverse Events - MedDRA Preferred Terms
By Decreasing Frequency
All Patients who Entered Study Period IV
F1J-MC-HMBU & HMCQ Study Period IV

Event	Dulox (N=195) n(%)	Venlafax (N=328) n(%)	Total (N=523) n(%)	Fishers Exact p-value	CMH p-value
Feeling abnormal	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Feeling cold	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Feeling jittery	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Flushing	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342

Frequent bowel movements	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Gait abnormal	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Gamma-glutamyltransferase increased	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Gastrointestinal disorder	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Haematochezia	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Hearing impaired	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Hepatitis toxic	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Herpes virus infection	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Hypersensitivity	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Hypokalaemia	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Increased tendency to bruise	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Influenza like illness	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Inner ear disorder	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Irritable bowel syndrome	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Joint dislocation	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Keratoconjunctivitis sicca	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Laryngitis	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Libido decreased	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Lower respiratory tract infection	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Lung disorder	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Major depression	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Mental disorder	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Metrorrhagia	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527

MedDRA version: 7.0
Baseline visits: 1-10, Postbaseline visits: 301-303
CMH = Cochran-Mantel-Haenszel test for general association, controlling for study.
Program: RMP.F1JSHMCQ.SASPGM(FQTAEG1C)
Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL & RMP.SAS.F1JM.L.MCHMCQSW.FINAL
1PRODUCTION DATA - PRODUCTION MODE

Treatment-Emergent Adverse Events - MedDRA Preferred Terms
By Decreasing Frequency
All Patients who Entered Study Period IV
F1J-MC-HMBU & HMCQ Study Period IV

Event	Dulox (N=195) n(%)	Venlafax (N=328) n(%)	Total (N=523) n(%)	Fishers Exact p-value	CMH p-value
Micturition urgency	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Motion sickness	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Muscle contracture	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Muscle spasms	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Muscle twitching	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114

Nervous system disorder	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Nervousness	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Night cramps	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Nocturia	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Otitis media	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Pain	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Panic attack	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Pneumonia	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Pregnancy	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Productive cough	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Prostatitis	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Pruritus generalised	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Restless legs syndrome	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Restlessness	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Rhinitis allergic	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Road traffic accident	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Sedation	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Skin laceration	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Speech disorder	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Subarachnoid haemorrhage	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Subcutaneous abscess	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Tachycardia	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293

MedDRA version: 7.0
Baseline visits: 1-10, Postbaseline visits: 301-303
CMH - Cochran-Mantel-Haenszel test for general association, controlling for study.
Program: RMP.F1J5HMCQ.SASPGM(FQTAEG1C)
Data: RMP.SAS.F1JM.L.MCHMBUSW.FINAL & RMP.SAS.F1JM.L.MCHMCQSW.FINAL
1PRODUCTION DATA - PRODUCTION MODE

Treatment-Emergent Adverse Events - MedDRA Preferred Terms
By Decreasing Frequency
All Patients who Entered Study Period IV
F1J-MC-HMBU & HMCQ Study Period IV

Event	Dulox (N=195) n(%)	Venlafax (N=328) n(%)	Total (N=523) n(%)	Fishers Exact p-value	CMH p-value
Tension	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Tension headache	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.527
Transaminases increased	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.293
Unintended pregnancy	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342
Urticaria	1(0.5%)	0(0.0%)	1(0.2%)	0.373	0.114
Viral labyrinthitis	0(0.0%)	1(0.3%)	1(0.2%)	1.000	0.342