

Table 1. Treatment-Emergent Adverse Experience Incidence in Placebo-Controlled Clinical Trials for Major Depressive Disorder¹

| Body System | Preferred Term | PAXIL (n = 421) | Placebo (n = 421) |
|-------------------|---|--------------------|----------------------|
| Body as a Whole | Headache | 18% | 17% |
| | Asthenia | 15% | 6% |
| Cardiovascular | Palpitation | 3% | 1% |
| | Vasodilation | 3% | 1% |
| Dermatologic | Sweating | 11% | 2% |
| | Rash | 2% | 1% |
| Gastrointestinal | Nausea | 26% | 9% |
| | Dry Mouth | 18% | 12% |
| | Constipation | 14% | 9% |
| | Diarrhea | 12% | 8% |
| | Decreased Appetite | 6% | 2% |
| | Flatulence | 4% | 2% |
| | Oropharynx Disorder ² | 2% | 0% |
| | Dyspepsia | 2% | 1% |
| Musculoskeletal | Myopathy | 2% | 1% |
| | Myalgia | 2% | 1% |
| | Myasthenia | 1% | 0% |
| Nervous System | Somnolence | 23% | 9% |
| | Dizziness | 13% | 6% |
| | Insomnia | 13% | 6% |
| | Tremor | 8% | 2% |
| | Nervousness | 5% | 3% |
| | Anxiety | 5% | 3% |
| | Paresthesia | 4% | 2% |
| | Libido Decreased | 3% | 0% |
| | Drugged Feeling | 2% | 1% |
| | Confusion | 1% | 0% |
| Respiration | Yawn | 4% | 0% |
| Special Senses | Blurred Vision | 4% | 1% |
| | Taste Perversion | 2% | 0% |
| Urogenital System | Ejaculatory Disturbance ^{3,4} | 13% | 0% |
| | Other Male Genital Disorders ^{3,5} | 10% | 0% |
| | Urinary Frequency | 3% | 1% |
| | Urination Disorder ⁶ | 3% | 0% |
| | Female Genital Disorders ^{3,7} | 2% | 0% |

1. Events reported by at least 1% of patients treated with PAXIL are included, except the following events which had an incidence on placebo \geq PAXIL: Abdominal pain, agitation, back pain, chest pain, CNS stimulation, fever, increased appetite, myoclonus, pharyngitis, postural hypotension, respiratory disorder (includes mostly “cold symptoms” or “URI”), trauma, and vomiting.
2. Includes mostly “lump in throat” and “tightness in throat.”