



**PAXIL® (paroxetine hydrochloride) Tablets and Oral Suspension**

(continued from other side)

	Major Depressive Disorder		OCD		Panic Disorder	
	PAXIL	Placebo	PAXIL	Placebo	PAXIL	Placebo
<b>Gastro-intestinal</b>						
Constipation	—	—	1.1%	0%	—	—
Nausea	3.2%	1.1%	1.9%	0%	3.2%	1.2%
Diarrhea	1.0%	0.3%	—	—	—	—
Dry mouth	1.0%	0.3%	—	—	—	—
Vomiting	1.0%	0.3%	—	—	—	—
Flatulence	—	—	—	—	—	—
<b>Other</b>						
Asthenia	1.6%	0.4%	1.9%	0.4%	—	—
Abnormal ejaculation <sup>1</sup>	1.6%	0%	2.1%	0%	—	—
Sweating	1.0%	0.3%	—	—	—	—
Impotence <sup>2</sup>	—	—	1.5%	0%	—	—
Libido Decreased	—	—	—	—	—	—

	Social Anxiety Disorder		Generalized Anxiety Disorder		PTSD	
	PAXIL	Placebo	PAXIL	Placebo	PAXIL	Placebo
<b>CNS</b>						
Somnolence	3.4%	0.3%	2.0%	0.2%	2.8%	0.6%
Insomnia	3.1%	0%	—	—	—	—
Agitation	—	—	—	—	1.0%	0.2%
Tremor	1.7%	0%	—	—	—	—
Anxiety	1.1%	0%	—	—	—	—
Dizziness	1.9%	0%	1.0%	0.2%	—	—
<b>Gastro-intestinal</b>						
Constipation	—	—	—	—	—	—
Nausea	4.0%	0.3%	2.0%	0.2%	2.2%	0.6%
Dry mouth	—	—	—	—	—	—
Vomiting	1.0%	0%	—	—	—	—
Flatulence	1.0%	0.3%	—	—	—	—
<b>Other</b>						
Asthenia	2.5%	0.6%	1.8%	0.2%	1.6%	0.2%
Abnormal ejaculation <sup>1</sup>	4.9%	0.6%	2.5%	0.5%	—	—
Sweating	1.1%	0%	1.1%	0.2%	—	—
Impotence <sup>2</sup>	—	—	—	—	—	—
Libido Decreased	—	—	—	—	—	—

Where numbers are not provided the incidence of the adverse events in patients treated with PAXIL was not >1% or was not greater than or equal to 2 times the incidence of placebo.

1. Incidence corrected for gender.

**Commonly Observed Adverse Events: Major Depressive Disorder:** The most commonly observed adverse events associated with the use of PAXIL at least twice that for placebo, derived from Table 2) were: Asthenia, sweating, nausea, decreased appetite, somnolence, dizziness, insomnia, tremor, nervousness, ejaculatory disturbance, and other male genital disorders.

**Obsessive Compulsive Disorder:** The most commonly observed adverse events associated with the use of paroxetine (incidence of 5% or greater and incidence for PAXIL at least twice that of placebo, derived from Table 2) were: Nausea, dry mouth, decreased appetite, constipation, dizziness, somnolence, tremor, sweating, impotence, and abnormal ejaculation.

**Panic Disorder:** The most commonly observed adverse events associated with the use of paroxetine (incidence of 5% or greater and incidence for PAXIL at least twice that of placebo, derived from Table 2) were: Asthenia, sweating, decreased appetite, libido decreased, tremor, abnormal ejaculation, female genital disorders, and impotence.

**Social Anxiety Disorder:** The most commonly observed adverse events associated with the use of paroxetine (incidence of 5% or greater and incidence for PAXIL at least twice that of placebo, derived from Table 2) were: Sweating, nausea, dry mouth, constipation, decreased appetite, somnolence, tremor, libido decreased, yawning, abnormal ejaculation, female genital disorders, and impotence.

**Generalized Anxiety Disorder:** The most commonly observed adverse events associated with the use of paroxetine (incidence of 5% or greater and incidence for PAXIL at least twice that of placebo, derived from Table 3) were: Asthenia, infection, constipation, decreased appetite, dry mouth, nausea, libido decreased, somnolence, tremor, sweating, and abnormal ejaculation.

**Posttraumatic Stress Disorder:** The most commonly observed adverse events associated with the use of paroxetine (incidence of 5% or greater and incidence for PAXIL at least twice that of placebo, derived from Table 3) were: Asthenia, sweating, nausea, dry mouth, diarrhea, decreased appetite, somnolence, decreased appetite, abnormal ejaculation, female genital disorders, and impotence.

**Incidence in Controlled Clinical Trials:** The prescriber should be aware that the figures in the tables following cannot be used to predict the incidence of side effects in the course of usual medical practice because of differences in patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and non-drug factors to the side effect incidence rate in the populations studied.

**Major Depressive Disorder:** Table 1 enumerates adverse events that occurred at an incidence of 1% or more among paroxetine-treated patients who participated in short-term (6-week) placebo-controlled trials in which patients were dosed in a range of 20 mg to 50 mg/day. Reported adverse events were classified using a standard COSTART-based Dictionary terminology.

**Table 1. Treatment-Emergent Adverse Experience Incidence in Placebo-Controlled Clinical Trials for Major Depressive Disorder<sup>1</sup>**

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	12%	9%
	Constipation	14%	9%
	Diarrhea	12%	8%
	Decreased Appetite	6%	2%
	Flatulence	2%	0%
	Oropharynx Disorder <sup>2</sup>	2%	0%
	Dyspepsia	2%	1%
Musculoskeletal	Dyspareunia	2%	1%
	Myalgia	2%	1%
	Myasthenia	1%	0%
Nervous System	Somnolence	23%	9%
	Dizziness	18%	1%
	Insomnia	13%	6%
	Tremor	8%	2%
	Nervousness	3%	2%
	Anxiety	5%	3%
	Paresthesia	4%	2%
	Libido Decreased	4%	2%
	Drugged Feeling	2%	1%
	Confusion	1%	0%
Respiration	Yawn	4%	0%
Special Senses	Burred Vision	2%	1%
	Taste Parversion	2%	0%
Urogenital System	Ejaculatory Disturbance <sup>3,4</sup>	13%	0%
	Other Male Genital Disorders <sup>5,6</sup>	10%	0%
	Urinary Frequency	1%	0%
	Urinary Incontinence <sup>6</sup>	3%	0%
	Female Genital Disorders <sup>7</sup>	2%	0%

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- Events reported by at least 1% of patients treated with PAXIL are included, except the following events which had an incidence on placebo > 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.
- Includes mostly "lump in throat" and "tightness in throat."
- Percentage corrected for gender.
- Mostly "ejaculatory delay."
- Includes "anorgasmia," "erectile difficulties," "delayed ejaculation/orgasm," and "sexual dysfunction," and "impotence."
- Includes mostly "difficultly with micturition" and "urinary hesitancy."
- Includes mostly "anorgasmia" and "difficulty reaching climax/orgasm."

**Obsessive Compulsive Disorder, Panic Disorder, and Social Anxiety Disorder:** Table 2 enumerates adverse events that occurred at a frequency of 2% or more among OCD patients on PAXIL who participated in placebo-controlled trials of 12-weeks duration in which patients were dosed in a range of 20 mg to 50 mg/day or among patients with panic disorder on PAXIL who participated in placebo-controlled trials of 10- to 12-weeks duration in which patients were dosed in a range of 10 mg to 50 mg/day or among patients with social anxiety disorder on PAXIL who participated in placebo-controlled trials of 12-weeks duration in which patients were dosed in a range of 20 mg to 50 mg/day.

**Table 2. Treatment-Emergent Adverse Experience Incidence in Placebo-Controlled Clinical Trials for Obsessive Compulsive Disorder, Panic Disorder, and Social Anxiety Disorder<sup>1</sup>**

	Obsessive Compulsive Disorder		Panic Disorder		Social Anxiety Disorder	
	PAXIL (n = 542)	Placebo (n = 265)	PAXIL (n = 469)	Placebo (n = 324)	PAXIL (n = 425)	Placebo (n = 339)
<b>Body System</b>						
Body as a Whole	Asthenia	22%	14%	14%	5%	22%
	Abdominal Pain	—	—	4%	3%	—
	Chest Pain	3%	2%	3%	2%	—
	Back Pain	2%	1%	2%	1%	—
	Trauma	2%	—	—	—	3%
Cardiovascular	Vasodilation	4%	1%	—	—	—
	Palpitation	2%	0%	—	—	—
Dermatologic	Sweating	9%	3%	14%	6%	9%
	Rash	3%	2%	—	—	2%
Gastro-intestinal	Nausea	23%	10%	23%	17%	25%
	Dry Mouth	18%	9%	18%	11%	9%
	Constipation	18%	6%	8%	8%	5%
	Diarrhea	10%	10%	12%	7%	9%
	Decreased Appetite	9%	3%	7%	3%	8%
	Dyspepsia	—	—	—	—	4%
	Flatulence	—	—	—	—	4%
	Impotence <sup>2</sup>	—	—	—	—	4%
	Appetite	4%	3%	2%	1%	—
	Vomiting	—	—	—	—	2%
Musculoskeletal	Myalgia	—	—	—	—	4%
Nervous System	Somnolence	24%	13%	18%	10%	21%
	Somnolence	24%	7%	19%	11%	22%
	Dizziness	12%	6%	14%	10%	11%
	Tremor	11%	3%	1%	8%	7%
	Nervousness	9%	8%	—	8%	7%
	Libido	7%	4%	9%	1%	12%
	Decreased Agitation	—	—	5%	4%	3%
	Anxiety	—	—	5%	4%	3%
	Impotence	—	—	—	—	4%
	Dreams	4%	1%	—	—	—
	Concentration	3%	2%	—	—	4%
	Impaired Depersonalization	3%	0%	—	—	—
	Myoclonus	3%	0%	3%	2%	2%
	Annesia	2%	1%	—	—	—
Respiratory System	Rhinitis	—	—	3%	0%	—
	Pharyngitis	—	—	—	—	4%
	Cough	—	—	—	—	5%
Special Senses	Abnormal Vision	4%	2%	—	—	4%
	Taste	2%	0%	—	—	1%
	Perversion	2%	0%	—	—	—
Urogenital System	Abnormal Ejaculation <sup>2</sup>	23%	1%	21%	1%	28%
	Dyspareunia	—	—	—	—	5%
	Female Genital Disorder <sup>3</sup>	3%	0%	9%	1%	9%
	Urinary Impotence <sup>4</sup>	8%	1%	5%	0%	5%
	Urinary Frequency	3%	1%	2%	0%	—
	Urinary Incontinence	3%	0%	—	—	—
	Impaired Urinary Tract Infection	2%	1%	2%	1%	—

1. Events reported by at least 2% of OCD, panic disorder, and social anxiety disorder in patients treated with PAXIL are included, except the following events which had an incidence on placebo > PAXIL: [OCD]: Abdominal pain, agitation, anxiety, back pain, cough increased, headache, hyperkinesia, infection, paresthesia, pharyngitis, respiratory disorder, rhinitis, and sinusitis. [panic disorder]: Abnormal dreams, abnormal vision, chest pain, cough increased, depersonalization, depression, dysmenorrhea, dyspepsia, flu syndrome, headache, infection, myalgia, nervousness, palpitation, paresthesia, pharyngitis, rash, respiratory disorder, sinusitis, taste perversion, trauma, urination impaired, and vasodilation. [social anxiety disorder]: Abdominal pain, depression, headache, infection, respiratory disorder, and sinusitis.

2. Percentage corrected for gender.

**Generalized Anxiety Disorder and Posttraumatic Stress Disorder:** Table 3 enumerates adverse events that occurred at a frequency of 2% or more among GAD patients on PAXIL who participated in placebo-controlled trials of 8-weeks duration in which patients were dosed in a range of 10 mg/day to 50 mg/day or among PTSD patients on PAXIL who participated in placebo-controlled trials of 12-weeks duration in which patients were dosed in a range of 20 mg/day to 50 mg/day.

**Table 3. Treatment-Emergent Adverse Experience Incidence in Placebo-Controlled Clinical Trials for Generalized Anxiety Disorder and Posttraumatic Stress Disorder<sup>1</sup>**

	Generalized Anxiety Disorder		Posttraumatic Stress Disorder	
	PAXIL (n = 735)	Placebo (n = 529)	PAXIL (n = 678)	Placebo (n = 504)
<b>Body System</b>				
Body as a Whole	Asthenia	14%	6%	12%
	Headache	17%	14%	5%
	Infection	6%	3%	5%
	Abdominal Pain	—	—	4%
	Trauma	—	—	6%
Cardiovascular	Vasodilation	3%	1%	2%
Dermatologic	Sweating	6%	2%	5%
Gastrointestinal	Nausea	20%	5%	19%
	Dry Mouth	11%	2%	8%
	Constipation	10%	2%	5%
	Diarrhea	9%	7%	11%
	Decreased Appetite	5%	1%	6%
	Vomiting	3%	2%	3%
	Dyspepsia	—	—	5%

1. Events reported by at least 2% of GAD and PTSD in patients treated with PAXIL are included, except the following events which had an incidence on placebo > PAXIL: [GAD]: Abdominal pain, agitation, anxiety, back pain, cough increased, headache, hyperkinesia, infection, paresthesia, pharyngitis, respiratory disorder, rhinitis, and sinusitis. [panic disorder]: Abnormal dreams, abnormal vision, chest pain, cough increased, depersonalization, depression, dysmenorrhea, dyspepsia, flu syndrome, headache, infection, myalgia, nervousness, palpitation, paresthesia, pharyngitis, rash, respiratory disorder, sinusitis, taste perversion, trauma, urination impaired, and vasodilation. [social anxiety disorder]: Abdominal pain, depression, headache, infection, respiratory disorder, and sinusitis.

2. Percentage corrected for gender.

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	Generalized Anxiety Disorder		Posttraumatic Stress Disorder	
	PAXIL (n = 735)	Placebo (n = 529)	PAXIL (n = 678)	Placebo (n = 504)
<b>Body System</b>				
Nervous System	Insomnia	11%	5%	12%
	Somnolence	15%	8%	16%
	Dizziness	6%	5%	6%
	Tremor	5%	1%	4%
	Nervousness	4%	3%	—
	Libido Decreased	9%	2%	5%
	Abnormal Dreams	7%	2%	3%
Respiratory System	Respiratory Disorder	7%	5%	—
	Sinusitis	4%	3%	—
	Yawn	4%	—	2%
Special Senses	Abnormal Vision	2%	1%	3%
Urogenital System	Abnormal Ejaculation <sup>2</sup>	25%	2%	13%
	Female Genital Disorder <sup>2</sup>	4%	1%	5%
	Impotence <sup>2</sup>	4%	3%	9%

1. Events reported by at least 2% of GAD and PTSD in patients treated with PAXIL are included, except the following events which had an incidence on placebo > PAXIL: [GAD]: Abdominal pain, back pain, trauma, dyspepsia, myalgia, and pharyngitis. [PTSD]: Back pain, headache, anxiety, depression, nervousness, respiratory disorder, pharyngitis, and sinusitis.

2. Percentage corrected for gender.

**Dose Dependency of Adverse Events:** A comparison of adverse event rates in a fixed-dose study comparing 10, 20, 30, and 40 mg/day of PAXIL with placebo in the treatment of major depressive disorder revealed a clear dose dependency for some of the more common adverse events associated with PAXIL, as shown in the following table.

**Table 4. Treatment-Emergent Adverse Experience Incidence in a Dose-Comparison Trial in the Treatment of Major Depressive Disorder<sup>1</sup>**

	Placebo n = 51	PAXIL			
		10 mg n = 102	20 mg n = 104	30 mg n = 101	40 mg n = 102
<b>Body System</b>					
Body as a Whole	Asthenia	0.0%	2.9%	10.6%	13.9%
Dermatology	Sweating	2.0%	1.0%	6.7%	8.9%
<b>Gastrointestinal</b>	Constipation	5.9%	4.9%	7.7%	9.9%
	Decreased Appetite	2.0%	2.0%	5.8%	4.0%
	Diarrhea	1.0%	9.8%	19.2%	7.9%
	Dry Mouth	2.0%	10.8%	18.3%	15.8%
	Nausea	13.7%	14.7%	26.9%	34.7%
<b>Nervous System</b>	Anxiety	0.0%	2.0%	5.8%	5.9%
	Dizziness	3.9%	6.9%	6.7%	8.9%
	Nervousness	0.0%	5.9%	5.8%	4.0%
	Paresthesia	0.0%	4.9%	4.0%	2.9%
	Somnolence	7.8%	12.7%	18.3%	20.8%
	Tremor	0.0%	0.0%	7.7%	7.9%
<b>Special Senses</b>	Burred Vision	2.0%	2.9%	2.9%	2.0%

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**RSC A/W  
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180 mm Measuring Bar

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