Cymbalta

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Cymbalta

Cymbalta Side Effects Center

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Cymbalta (duloxetine) is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) used for treating depression, anxiety disorder, and pain associated with diabetic peripheral neuropathy or fibromyalgia. The most common side effects of Cymbalta are nausea, dry mouth, constipation, diarrhea, fatigue, drowsiness, difficulty sleeping, loss of appetite, and dizziness. Some patients may experience withdrawal reactions such anxiety, nausea, nervousness, and insomnia.

The recommended dose of Cymbalta for treating depression is 20 or 30 mg twice daily or 60 mg once daily. Cymbalta should not be used in combination with monoamine oxidase inhibitors (MAOI) (for example, phenelzine [Nardil]). At least 5 days should be allowed after

Prescribing Information

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For Patients

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Health Resources

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Related Supplements

Fish Oil
Lithium
Melatonin
St. John's Wort
Zinc

stopping Cymbalta before starting an MAOI. There are no adequate studies in pregnant women. Cymbalta is excreted into the milk of lactating women.

Our Cymbalta Side Effects Drug Center provides a comprehensive view of available drug information on the potential side effects when taking this medication.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Cymbalta in Detail - Patient Information: Side Effects

Get emergency medical help if you have any of these **signs of an allergic reaction:** skin rash or hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Report any new or worsening symptoms to your doctor, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Call your doctor at once if you have:

- nausea, upper stomach pain, itching, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes);
- feeling like you might pass out;
- agitation, hallucinations, fever, fast heart rate, overactive reflexes, vomiting, diarrhea, loss of coordination;
- very stiff (rigid) muscles, high fever, sweating, confusion, tremors;
- easy bruising, unusual bleeding;
- painful or difficult urination;
- headache, trouble concentrating, memory problems, weakness, feeling unsteady, seizure, shallow breathing or breathing that stops; or
- severe skin reaction -- fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.

Other common side effects may include:

- dry mouth;
- drowsiness;
- tired feeling;
- mild nausea or loss of appetite; or
- constipation.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Read the entire detailed patient monograph for Cymbalta (Duloxetine Hcl)

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Cymbalta Overview - Patient Information: Side Effects

SIDE EFFECTS: See also Warning section.
Nausea, dry mouth, constipation, loss of appetite, tiredness, drowsiness, or increased sweating may occur. If any of these effects persist or worsen, tell your doctor promptly.

Dizziness or lightheadedness may occur, especially when you first start or increase your dose of this drug. To reduce the risk of dizziness, lightheadedness, or falling, get up slowly when rising from a sitting or lying position.

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Type 2 Diabetes Warning Signs

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Duloxetine may increase your blood pressure. Check your blood pressure regularly and tell your doctor of any high results.

Tell your doctor right away if any of these serious side effects occur: confusion, easy bruising/bleeding, decreased interest in sex, changes in sexual ability, muscle cramps/weakness, shaking (tremor), difficulty urinating, unusual decrease in the amount of urine, signs of liver problems (such as stomach/abdominal pain, persistent nausea, vomiting, yellowing eyes/skin, dark urine).

Get medical help right away if you have any very serious side effects, including: black/bloody stools, vomit that looks like coffee grounds, seizure, eye pain/swelling/redness, vision changes (such as seeing rainbows around lights at night, blurred vision).

This medication may increase serotonin and rarely cause a very serious condition called serotonin syndrome/toxicity. The risk increases if you are also taking other drugs that increase serotonin, so tell your doctor or pharmacist of all the drugs you take (see Drug Interactions section). Get medical help right away if you develop some of the following symptoms: fast heartbeat, hallucinations, loss of coordination, severe dizziness, severe nausea/vomiting/diarrhea, twitching muscles, unexplained fever, unusual agitation/restlessness.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing, skin blisters, mouth sores.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

Read the entire patient information overview for Cymbalta (Duloxetine Hcl)

Learn More »

Cymbalta FDA Prescribing Information: Side Effects (Adverse Reactions)

SIDE EFFECTS

The following serious adverse reactions are described below and elsewhere in the labeling:

- Suicidal Thoughts and Behaviors in Children, Adolescents and Young Adults [see **BOXED WARNING** and **WARNINGS AND PRECAUTIONS**]
- Hepatotoxicity [see **WARNINGS AND PRECAUTIONS**]
- Orthostatic Hypotension, Falls and Syncope [see **WARNINGS AND PRECAUTIONS**]
- Serotonin Syndrome [see **WARNINGS AND PRECAUTIONS**]
- Abnormal Bleeding [see **WARNINGS AND PRECAUTIONS**]
- Severe Skin Reactions [see **WARNINGS AND PRECAUTIONS**]
- Discontinuation of Treatment with CYMBALTA [see **WARNINGS AND PRECAUTIONS**]
- Activation of Mania/Hypomania [see **WARNINGS AND PRECAUTIONS**]
- Angle-Closure Glaucoma [see **WARNINGS AND PRECAUTIONS**]
- Seizures [see **WARNINGS AND PRECAUTIONS**]

- Effect on Blood Pressure [see **WARNINGS AND PRECAUTIONS**]
- Clinically Important Drug Interactions [see **WARNINGS AND PRECAUTIONS**]
- Hyponatremia [see **WARNINGS AND PRECAUTIONS**]
- Urinary Hesitation and Retention [see **WARNINGS AND PRECAUTIONS**]

Clinical Trial Data Sources

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The stated frequencies of adverse reactions represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse reaction of the type listed. A reaction was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. Reactions reported during the studies were not necessarily caused by the therapy, and the frequencies do not reflect investigator impression (assessment) of causality.

Adults

The data described below reflect exposure to CYMBALTA in placebo-controlled trials for MDD (N=3779), GAD (N=1018), OA (N=503), CLBP (N=600), DPNP (N=906), and FM (N=1294). The population studied was 17 to 89 years of age; 65.7%, 60.8%, 60.6%, 42.9%, and 94.4% female; and 81.8%, 72.6%, 85.3%, 74.0%, and 85.7% Caucasian for MDD, GAD, OA and CLBP, DPNP, and FM, respectively. Most patients received doses of a total of 60 to 120 mg per day [see **Clinical Studies**].The data below do not include results of the trial examining the efficacy of CYMBALTA in patients ≥ 65 years old for the treatment of generalized anxiety disorder; however, the adverse reactions observed in this geriatric sample were generally similar to adverse reactions in the overall adult population.

Children and Adolescents

The data described below reflect exposure to CYMBALTA in pediatric, 10-week, placebo-controlled trials for MDD (N=341) and GAD (N=135). The population studied (N=476) was 7 to 17 years of age with 42.4% children age 7 to 11 years of age, 50.6% female, and 68.6% white. Patients received 30-120 mg per day during placebo-controlled acute treatment studies. Additional data come from the overall total of 822 pediatric patients (age 7 to 17 years of age) with 41.7% children age 7 to 11 years of age and 51.8% female exposed to CYMBALTA in MDD and GAD clinical trials up to 36-weeks in length, in which most patients received 30-120 mg per day.

Adverse Reactions Reported As Reasons For Discontinuation Of Treatment In Adult Placebo-Controlled Trials

Major Depressive Disorder

Approximately 8.4% (319/3779) of the patients who received CYMBALTA in placebo-controlled trials for MDD discontinued treatment due to an adverse reaction, compared with 4.6% (117/2536) of the patients receiving placebo. Nausea (CYMBALTA 1.1%, placebo 0.4%) was the only common adverse reaction reported as a reason for discontinuation and considered to be drug-related (i.e., discontinuation occurring in at least 1% of the CYMBALTA-treated patients and at a rate of at least twice that of placebo).

Generalized Anxiety Disorder

Approximately 13.7% (139/1018) of the patients who received CYMBALTA in placebo-controlled trials for GAD discontinued treatment due to an adverse reaction, compared with 5.0% (38/767) for placebo. Common adverse reactions reported as a reason for discontinuation and considered to be drug-related (as defined above) included nausea (CYMBALTA 3.3%, placebo 0.4%), and dizziness (CYMBALTA 1.3%, placebo 0.4%).

Diabetic Peripheral Neuropathic Pain

Approximately 12.9% (117/906) of the patients who received CYMBALTA in placebo-controlled trials for DPNP discontinued treatment due to an adverse reaction, compared with 5.1% (23/448) for placebo. Common adverse reactions reported as a reason for discontinuation and considered to be drug-related (as defined above) included nausea (CYMBALTA 3.5%, placebo 0.7%), dizziness (CYMBALTA 1.2%, placebo 0.4%), and somnolence (CYMBALTA 1.1%, placebo 0.0%).

Fibromyalgia

Approximately 17.5% (227/1294) of the patients who received CYMBALTA in 3 to 6 month placebo-controlled trials for FM discontinued treatment due to an adverse reaction, compared with 10.1% (96/955) for placebo. Common adverse reactions reported as a reason for discontinuation and considered to be drug-related (as defined above) included nausea (CYMBALTA 2.0%, placebo 0.5%), headache (CYMBALTA 1.2%, placebo 0.3%), somnolence (CYMBALTA 1.1%, placebo 0.0%), and fatigue (CYMBALTA 1.1%, placebo 0.1%).

Chronic Pain due to Osteoarthritis

Approximately 15.7% (79/503) of the patients who received CYMBALTA in 13-week, placebo-controlled trials for chronic pain due to OA discontinued treatment due to an adverse reaction, compared with 7.3% (37/508) for placebo. Common adverse reactions reported as a reason for discontinuation and considered to be drug-related (as defined above) included nausea (CYMBALTA 2.2%, placebo 1.0%).

Chronic Low Back Pain

Approximately 16.5% (99/600) of the patients who received CYMBALTA in 13-week, placebo-controlled trials for CLBP discontinued treatment due to an adverse reaction, compared with 6.3% (28/441) for placebo. Common adverse reactions reported as a reason for discontinuation and considered to be drug-related (as defined above) included nausea (CYMBALTA 3.0%, placebo 0.7%), and somnolence (CYMBALTA 1.0%, placebo 0.0%).

Most Common Adult Adverse Reactions

Pooled Trials for all Approved Indications

The most commonly observed adverse reactions in CYMBALTA-treated patients (incidence of at least 5% and at least twice the incidence in placebo patients) were nausea, dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

Diabetic Peripheral Neuropathic Pain

The most commonly observed adverse reactions in CYMBALTA-treated patients (as defined above) were nausea, somnolence, decreased appetite, constipation, hyperhidrosis, and dry mouth.

Fibromyalgia

The most commonly observed adverse reactions in CYMBALTA-treated patients (as defined above) were nausea, dry mouth, constipation, somnolence, decreased appetite, hyperhidrosis, and agitation.

Chronic Pain due to Osteoarthritis

The most commonly observed adverse reactions in CYMBALTA-treated patients (as defined above) were nausea, fatigue, constipation, dry mouth, insomnia, somnolence, and dizziness.

Chronic Low Back Pain

The most commonly observed adverse reactions in CYMBALTA-treated patients (as defined above) were nausea, dry mouth, insomnia, somnolence, constipation, dizziness, and fatigue.

Adverse Reactions Occurring At An Incidence Of 5% Or More Among CYMBALTA-Treated Patients In Adult Placebo-Controlled Trials

Table 2 gives the incidence of treatment-emergent adverse reactions in placebo-controlled trials for approved indications that occurred in 5% or

more of patients treated with CYMBALTA and with an incidence greater than placebo.

Table 2: Treatment-Emergent Adverse Reactions: Incidence of 5% or More and Greater than Placebo in Placebo-Controlled Trials of Approved Indications[a]

ADVERSE REACTION	PERCENTAGE OF PATIENTS REPORTING REACTION	
	CYMBALTA (N=8100)	PLACEBO (N=5655)
Nausea[c]	23	8
Headache	14	12
Dry mouth	13	5
Somnolence[e]	10	3
Fatigue[b,c]	9	5
Insomnia[d]	9	5
Constipation[c]	9	4
Dizziness[c]	9	5
Diarrhea	9	6
Decreased appetite[c]	7	2
Hyperhidrosis[c]	6	1
Abdominal pain[f]	5	4

[a]The inclusion of an event in the table is determined based on the percentages before rounding; however, the percentages displayed in the table are rounded to the nearest integer.

[b]Also includes asthenia.

[c]Events for which there was a significant dose-dependent relationship in fixed-dose studies, excluding three MDD studies which did not have a placebo lead-in period or dose titration.

[d]Also includes initial insomnia, middle insomnia, and early morning awakening.

[e]Also includes hypersomnia and sedation.

[f]Also includes abdominal discomfort, abdominal pain lower, abdominal pain upper, abdominal tenderness, and gastrointestinal pain.

Adverse Reactions Occurring At An Incidence Of 2% Or More Among CYMBALTA-Treated Patients In Adult Placebo-Controlled Trials

Pooled MDD and GAD Trials

Table 3 gives the incidence of treatment-emergent adverse reactions in MDD and GAD placebo-controlled trials for approved indications that occurred in 2% or more of patients treated with CYMBALTA and with an incidence greater than placebo.

Table 3: Treatment-Emergent Adverse Reactions: Incidence of 2% or More and Greater than Placebo in MDD and GAD Placebo-Controlled Trials[a,b]

SYSTEM ORGAN CLASS / ADVERSE REACTION	PERCENTAGE OF PATIENTS REPORTING REACTION	
	CYMBALTA (N=4797)	PLACEBO (N=3303)
Cardiac Disorders		
Palpitations	2	1
Eye Disorders		
Vision blurred	3	1
Gastrointestinal Disorders		
Nausea[c]	23	8
Dry mouth	14	6

Constipation[c]	9	4
Diarrhea	9	6
Abdominal pain[d]	5	4
Vomiting	4	2
General Disorders and Administration Site Conditions		
Fatigue[e]	9	5
Metabolism and Nutrition Disorders		
Decreased appetite[c]	6	2
Nervous System Disorders		
Headache	14	14
Dizziness[c]	9	5
Somnolence†	9	3
Tremor	3	1
Psychiatric Disorders		
Insomnia[g]	9	5
Agitation[h]	4	2
Anxiety	3	2
Reproductive System and Breast Disorders		
Erectile dysfunction	4	1
Ejaculation delayed[c]	2	1
Libido decreased[i]	3	1
Orgasm abnormal[j]	2	< 1
Respiratory, Thoracic, and Mediastinal Disorders		
Yawning	2	< 1
Skin and Subcutaneous Tissue Disorders		
Hyperhidrosis	6	2

[a]The inclusion of an event in the table is determined based on the percentages before rounding; however, the percentages displayed in the table are rounded to the nearest integer.

[b]For GAD, there were no adverse events that were significantly different between treatments in adults ≥ 65 years that were also not significant in the adults < 65 years.

[c]Events for which there was a significant dose-dependent relationship in fixed-dose studies, excluding three MDD studies which did not have a placebo lead-in period or dose titration.

[d]Also includes abdominal pain upper, abdominal pain lower, abdominal tenderness, abdominal discomfort, and gastrointestinal pain

[e]Also includes asthenia

[f]Also includes hypersomnia and sedation

[g]Also includes initial insomnia, middle insomnia, and early morning awakening

[h]Also includes feeling jittery, nervousness, restlessness, tension and psychomotor hyperactivity

[i]Also includes loss of libido

[j]Also includes anorgasmia

DPNP, FM, OA, and CLBP

Table 4 gives the incidence of treatment-emergent adverse events that occurred in 2% or more of patients treated with CYMBALTA (determined prior to rounding) in the premarketing acute phase of DPNP, FM, OA, and CLBP placebo-controlled trials and with an incidence greater than placebo.

Table 4: Treatment-Emergent Adverse Reactions: Incidence of 2% or More and Greater than Placebo in DPNP, FM, OA, and CLBP Placebo-Controlled Trials[a]

SYSTEM ORGAN CLASS / ADVERSE REACTION	PERCENTAGE OF PATIENTS REPORTING REACTION	
	CYMBALTA	PLACEBO

	(N=3303)	(N=2352)
Gastrointestinal Disorders		
Nausea	23	7
Dry Mouth[b]	11	3
Constipation[b]	10	3
Diarrhea	9	5
Abdominal Pain[c]	5	4
Vomiting	3	2
Dyspepsia	2	1
General Disorders and Administration Site Conditions		
Fatigue[d]	11	5
Infections and Infestations		
Nasopharyngitis	4	4
Upper Respiratory Tract Infection	3	3
Influenza	2	2
Metabolism and Nutrition Disorders		
Decreased Appetite[b]	8	1
Musculoskeletal and Connective Tissue		
Musculoskeletal Pain[e]	3	3
Muscle Spasms	2	2
Nervous System Disorders		
Headache	13	8
Somnolence[b,†]	11	3
Dizziness	9	5
Paraesthesia[g]	2	2
Tremor[b]	2	< 1
Psychiatric Disorders		
Insomnia[b,h]	10	5
Agitation[i]	3	1
Reproductive System and Breast Disorders		
Erectile Dysfunction[b]	4	< 1
Ejaculation Disorder[j]	2	< 1
Respiratory, Thoracic, and Mediastinal Disorders		
Cough	2	2
Skin and Subcutaneous Tissue Disorders		
Hyperhidrosis	6	1
Vascular Disorders		
Flushing[k]	3	1
Blood pressure increased[l]	2	1

[a]The inclusion of an event in the table is determined based on the percentages before rounding; however, the percentages displayed in the table are rounded to the nearest integer.

[b]Incidence of 120 mg/day is significantly greater than the incidence for 60 mg/day.

[c]Also includes abdominal discomfort, abdominal pain lower, abdominal pain upper, abdominal tenderness and gastrointestinal pain

[d]Also includes asthenia

[e]Also includes myalgia and neck pain

[f]Also includes hypersomnia and sedation

[g]Also includes hypoaesthesia, hypoaesthesia facial, genital hypoaesthesia and paraesthesia

oral

[h]Also includes initial insomnia, middle insomnia, and early morning awakening.

[i]Also includes feeling jittery, nervousness, restlessness, tension and psychomotor hyperactivity

[j]Also includes ejaculation failure

[k]Also includes hot flush

[l]Also includes blood pressure diastolic increased, blood pressure systolic increased, diastolic hypertension, essential hypertension, hypertension, hypertensive crisis, labile hypertension, orthostatic hypertension, secondary hypertension, and systolic hypertension

Effects On Male And Female Sexual Function In Adults

Changes in sexual desire, sexual performance and sexual satisfaction often occur as manifestations of psychiatric disorders or diabetes, but they may also be a consequence of pharmacologic treatment. Because adverse sexual reactions are presumed to be voluntarily underreported, the Arizona Sexual Experience Scale (ASEX), a validated measure designed to identify sexual side effects, was used prospectively in 4 MDD placebo-controlled trials. In these trials, as shown in Table 5 below, patients treated with CYMBALTA experienced significantly more sexual dysfunction, as measured by the total score on the ASEX, than did patients treated with placebo. Gender analysis showed that this difference occurred only in males. Males treated with CYMBALTA experienced more difficulty with ability to reach orgasm (ASEX Item 4) than males treated with placebo. Females did not experience more sexual dysfunction on CYMBALTA than on placebo as measured by ASEX total score. Negative numbers signify an improvement from a baseline level of dysfunction, which is commonly seen in depressed patients. Physicians should routinely inquire about possible sexual side effects.

Table 5: Mean Change in ASEX Scores by Gender in MDD Placebo-Controlled Trials

	MALE PATIENTS[A]		FEMALE PATIENTS[B]	
	CYMBALTA (N=175)	PLACEBO (N=83)	CYMBALTA (N=241)	PLACEBO (N=126)
ASEX Total (Items 1-5)	0.56[b]	-1.07	-1.15	-1.07
Item 1 — Sex drive	-0.07	-0.12	-0.32	-0.24
Item 2 — Arousal	0.01	-0.26	-0.21	-0.18
Item 3 — Ability to achieve erection (men); Lubrication (women)	0.03	-0.25	-0.17	-0.18
Item 4 — Ease of reaching orgasm	0.40[c]	-0.24	-0.09	-0.13
Item 5 — Orgasm satisfaction	0.09	-0.13	-0.11	-0.17

[a]n=Number of patients with non-missing change score for ASEX total

[b]p=0.013 versus placebo

[c]p < 0.001 versus placebo

Vital Sign Changes In Adults

In placebo-controlled clinical trials across approved indications for change from baseline to endpoint, CYMBALTA treatment was associated with mean increases of 0.23 mm Hg in systolic blood pressure and 0.73 mm Hg in diastolic blood pressure compared to mean decreases of 1.09 mm Hg systolic and 0.55 mm Hg diastolic in placebo-treated patients. There was no significant difference in the frequency of sustained (3 consecutive visits) elevated blood pressure [see **WARNINGS AND PRECAUTIONS**].

CYMBALTA treatment, for up to 26 weeks in placebo-controlled trials across approved indications, typically caused a small increase in heart rate for change from baseline to endpoint compared to placebo of up to 1.37 beats per minute (increase of 1.20 beats per minute in CYMBALTA -treated patients, decrease of 0.17 beats per minute in placebo-treated patients).

Laboratory Changes In Adults

CYMBALTA treatment in placebo-controlled clinical trials across approved indications, was associated with small mean increases from baseline to endpoint in ALT, AST, CPK, and alkaline phosphatase; infrequent, modest, transient, abnormal values were observed for these analytes in CYMBALTA-treated patients when compared with placebo-treated patients [see **WARNINGS AND PRECAUTIONS**]. High bicarbonate, cholesterol, and abnormal (high or low) potassium, were observed more frequently in CYMBALTA treated patients compared to placebo.

Electrocardiogram Changes In Adults

The effect of CYMBALTA 160 mg and 200 mg administered twice daily to steady state was evaluated in a randomized, double-blinded, two-way crossover study in 117 healthy female subjects. No QT interval prolongation was detected. CYMBALTA appears to be associated with concentration-dependent but not clinically meaningful QT shortening.

Other Adverse Reactions Observed During The Premarketing And Postmarketing Clinical Trial Evaluation Of CYMBALTA In Adults

Following is a list of treatment-emergent adverse reactions reported by patients treated with CYMBALTA in clinical trials. In clinical trials of all indications, 34,756 patients were treated with CYMBALTA. Of these, 26.9% (9337) took CYMBALTA for at least 6 months, and 12.4% (4317) for at least one year. The following listing is not intended to include reactions (1) already listed in previous tables or elsewhere in labeling, (2) for which a drug cause was remote, (3) which were so general as to be uninformative, (4) which were not considered to have significant clinical implications, or (5) which occurred at a rate equal to or less than placebo.

Reactions are categorized by body system according to the following definitions: frequent adverse reactions are those occurring in at least 1/100 patients; infrequent adverse reactions are those occurring in 1/100 to 1/1000 patients; rare reactions are those occurring in fewer than 1/1000 patients.

Cardiac Disorders - *Frequent*: palpitations; *Infrequent*: myocardial infarction and tachycardia.

Ear and Labyrinth Disorders - *Frequent*: vertigo; *Infrequent*: ear pain and tinnitus.

Endocrine Disorders - *Infrequent*: hypothyroidism.

Eye Disorders - *Frequent*: vision blurred; *Infrequent*: diplopia, dry eye, and visual impairment.

Gastrointestinal Disorders - *Frequent*: flatulence; *Infrequent*: dysphagia, eructation, gastritis, gastrointestinal hemorrhage, halitosis, and stomatitis; *Rare*: gastric ulcer.

General Disorders and Administration Site Conditions - *Frequent*: chills/rigors; *Infrequent*: falls, feeling abnormal, feeling hot and/or cold, malaise, and thirst; *Rare*: gait disturbance.

Infections and Infestations - *Infrequent*: gastroenteritis and laryngitis.

Investigations - *Frequent*: weight increased, weight decreased; *Infrequent*: blood cholesterol increased.

Metabolism and Nutrition Disorders - *Infrequent*: dehydration and hyperlipidemia; *Rare*: dyslipidemia.

Musculoskeletal and Connective Tissue Disorders - *Frequent*: musculoskeletal pain; *Infrequent*: muscle tightness and muscle twitching.

Nervous System Disorders - *Frequent*: dysgeusia, lethargy, and paraesthesia/hypoesthesia; *Infrequent*: disturbance in attention, dyskinesia, myoclonus, and poor quality sleep; *Rare*: dysarthria.

Psychiatric Disorders - *Frequent*: abnormal dreams and sleep disorder; *Infrequent*: apathy, bruxism, disorientation/confusional state, irritability, mood swings, and suicide attempt; *Rare*: completed suicide.

Renal and Urinary Disorders - *Frequent*: urinary frequency; *Infrequent*: dysuria, micturition urgency, nocturia, polyuria, and urine odor abnormal.

Reproductive System and Breast Disorders - *Frequent*:

anorgasmia/orgasm abnormal; *Infrequent*: menopausal symptoms, sexual dysfunction, and testicular pain; *Rare*: menstrual disorder.

Respiratory, Thoracic and Mediastinal Disorders - *Frequent*: yawning, oropharyngeal pain; *Infrequent*: throat tightness.

Skin and Subcutaneous Tissue Disorders - *Frequent*: pruritus; *Infrequent*: cold sweat, dermatitis contact, erythema, increased tendency to bruise, night sweats, and photosensitivity reaction; *Rare*: ecchymosis.

Vascular Disorders - *Frequent*: hot flush; *Infrequent*: flushing, orthostatic hypotension, and peripheral coldness.

Adverse Reactions Observed In Children And Adolescent Placebo-Controlled Clinical Trials

The adverse drug reaction profile observed in pediatric clinical trials (children and adolescents) was consistent with the adverse drug reaction profile observed in adult clinical trials. The specific adverse drug reactions observed in adult patients can be expected to be observed in pediatric patients (children and adolescents) [see **Adverse Reactions Occurring at an Incidence of 2% or More Among CYMBALTA-Treated Patients in Adult Placebo-Controlled Trials** above]. The most common (≥ 5% and twice placebo) adverse reactions observed in pediatric clinical trials include: nausea, diarrhea, decreased weight, and dizziness.

Table 6 provides the incidence of treatment-emergent adverse reactions in MDD and GAD pediatric placebo-controlled trials that occurred in greater than 2% of patients treated with CYMBALTA and with an incidence greater than placebo.

Table 6: Treatment-Emergent Adverse Reactions: Incidence of 2% or More and Greater than Placebo in three 10week Pediatric Placebo-Controlled Trials[a]

SYSTEM ORGAN CLASS/ADVERSE REACTION	PERCENTAGE OF PEDIATRIC PATIENTS REPORTING REACTION	
	CYMBALTA (N=476)	PLACEBO (N=362)
Gastrointestinal Disorders		
Nausea	18	8
Abdominal Pain[b]	13	10
Vomiting	9	4
Diarrhea	6	3
Dry Mouth	2	1
General Disorders and Administration Site Conditions		
Fatigue[c]	7	5
Investigations		
Decreased Weight[d]	14	6
Metabolism and Nutrition Disorders		
Decreased Appetite	10	5
Nervous System Disorders		
Headache	18	13
Somnolence[e]	11	6
Dizziness	8	4
Psychiatric Disorders		
Insomnia[f]	7	4
Respiratory, Thoracic, and Mediastinal Disorders		
Oropharyngeal Pain	4	2
Cough	3	1

[a]The inclusion of an event in the table is determined based on the percentages before

rounding; however, the percentages displayed in the table are rounded to the nearest integer.

[b]Also includes abdominal pain upper, abdominal pain lower, abdominal tenderness, abdominal discomfort, and gastrointestinal pain.

[c]Also includes asthenia.

[d]Frequency based on weight measurement meeting potentially clinically significant threshold of ≥ 3.5% weight loss (N=467 CYMBALTA; N=354 Placebo).

[e]Also includes hypersomnia and sedation.

[f]Also includes initial insomnia, insomnia, middle insomnia, and terminal insomnia.

Other adverse reactions that occurred at an incidence of less than 2% but were reported by more CYMBALTA treated patients than placebo treated patients and are associated CYMBALTA treatment: abnormal dreams (including nightmare), anxiety, flushing (including hot flush), hyperhidrosis, palpitations, pulse increased, and tremor.

Discontinuation-emergent symptoms have been reported when stopping CYMBALTA. The most commonly reported symptoms following discontinuation of CYMBALTA in pediatric clinical trials have included headache, dizziness, insomnia, and abdominal pain [see **WARNINGS AND PRECAUTIONS** and **Adverse Reactions Occurring at an Incidence of 2% or More Among CYMBALTA-Treated Patients in Adult Placebo-Controlled Trials** above].

Growth (Height and Weight)

Decreased appetite and weight loss have been observed in association with the use of SSRIs and SNRIs. Pediatric patients treated with CYMBALTA in clinical trials experienced a 0.1kg mean decrease in weight at 10 weeks, compared with a mean weight gain of approximately 0.9 kg in placebo-treated patients. The proportion of patients who experienced a clinically significant decrease in weight (≥ 3.5%) was greater in the CYMBALTA group than in the placebo group (14% and 6%, respectively). Subsequently, over the 4- to 6-month uncontrolled extension periods, CYMBALTA-treated patients on average trended toward recovery to their expected baseline weight percentile based on population data from age- and sex-matched peers. In studies up to 9 months, CYMBALTA-treated pediatric patients experienced an increase in height of 1.7 cm on average (2.2 cm increase in children [7 to 11 years of age] and 1.3 cm increase in adolescents [12 to 17 years of age]). While height increase was observed during these studies, a mean decrease of 1% in height percentile was observed (decrease of 2% in children [7 to 11 years of age] and increase of 0.3% in adolescents [12 to 17 years of age]). Weight and height should be monitored regularly in children and adolescents treated with CYMBALTA.

Postmarketing Spontaneous Reports

The following adverse reactions have been identified during post approval use of CYMBALTA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions reported since market introduction that were temporally related to CYMBALTA therapy and not mentioned elsewhere in labeling include: anaphylactic reaction, aggression and anger (particularly early in treatment or after treatment discontinuation), angioneurotic edema, angle-closure glaucoma, colitis (microscopic or unspecified), cutaneous vasculitis (sometimes associated with systemic involvement), extrapyramidal disorder, galactorrhea, gynecological bleeding, hallucinations, hyperglycemia, hyperprolactinemia, hypersensitivity, hypertensive crisis, muscle spasm, rash, restless legs syndrome, seizures upon treatment discontinuation, supraventricular arrhythmia, tinnitus (upon treatment discontinuation), trismus, and urticaria.

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