

duloxetine (Rx) Brand and Other Names: Cymbalta

- Classes: Antidepressants, SNRIs;
- Fibromyalgia Agents

Patient Handout

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Patient Education
duloxetine oral

IMPORTANT: HOW TO USE THIS INFORMATION: This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

DULOXETINE - ORAL

(doo-LOX-e-teen)

COMMON BRAND NAME(S): Cymbalta

WARNING: Antidepressant medications are used to treat a variety of conditions, including depression and other mental/mood disorders. These medications can help prevent suicidal thoughts/attempts and provide other important benefits. However, a small number of people (especially people younger than 25) who take antidepressants for any condition may experience worsening depression, other mental/mood symptoms, or suicidal thoughts/attempts. Therefore, it is very important to talk with the doctor about the risks and benefits of antidepressant medication (especially for people younger than 25), even if treatment is not for a mental/mood condition.

Tell the doctor immediately if you notice worsening depression/other psychiatric conditions, unusual behavior changes (including possible suicidal thoughts/attempts), or other mental/mood changes (including new/worsening anxiety, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, very rapid speech). Be especially watchful for these symptoms when a new antidepressant is started or when the dose is changed.

USES:

Duloxetine is used to treat depression and anxiety. In addition, duloxetine is used to help relieve nerve pain (peripheral neuropathy) in people with diabetes or ongoing pain due to medical conditions such as arthritis, chronic back pain, or fibromyalgia (a condition that causes widespread pain).

Duloxetine may improve your mood, sleep, appetite, and energy level, and decrease nervousness. It can also decrease pain due to certain medical conditions. Duloxetine is known as a serotonin-norepinephrine reuptake inhibitor (SNRI). This medication works by helping to restore the balance of certain natural substances (serotonin and norepinephrine) in the brain.

HOW TO USE:

Read the Medication Guide and, if available, the Patient Information Leaflet provided by your pharmacist before you start using duloxetine and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication by mouth as directed by your doctor, usually 1 or 2 times a day with or without food. If you have nausea, it may help to take this drug with food. Swallow the capsule whole. Do not crush or chew the capsule or mix the contents with food or liquid. Doing so can release all of the drug at once, increasing the risk of side effects.

The dosage is based on your age, medical condition and response to treatment. To reduce your risk of side effects, your doctor may direct you to start this medication at a low dose and gradually increase your dose. Follow your doctor's instructions carefully. Take this medication regularly to get the most benefit from it. To help you remember, take it at the same time(s) each day.

It is important to continue taking this medication as prescribed even if you feel well. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when this drug is suddenly stopped. Also, you may experience symptoms such as dizziness, confusion, mood swings, headache, tiredness, diarrhea, sleep changes, and brief feelings similar to electric shock. Your dose may need to be gradually decreased to reduce side effects. Report any new or worsening symptoms immediately.

Tell your doctor if your condition persists or worsens.

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.

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.

This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high.

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.

PRECAUTIONS:

Before taking duloxetine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: personal or family history of psychiatric disorders (such as bipolar/manic-depressive disorder), personal or family history of suicide attempts, bleeding problems, personal or family history of glaucoma (angle-closure type), high blood pressure, kidney disease, liver disease, seizure disorder, stomach problems (such as slow emptying of the stomach), use/abuse of alcohol.

This drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Avoid alcoholic beverages.

If you have diabetes, duloxetine may affect your blood sugar levels. Check your blood sugar levels regularly as directed by your doctor. Your doctor may need to adjust your diabetes medication, exercise program, or diet.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Older adults may be more sensitive to the side effects of this drug, especially bleeding, dizziness, lightheadedness, or loss of coordination. Older adults may also be more likely to develop a type of salt imbalance (hyponatremia), especially if they are taking "water pills" (diuretics). Dizziness, lightheadedness, or loss of coordination can increase the risk of falling.

Children may be more sensitive to the side effects of this drug, especially loss of appetite and weight loss. Monitor weight and height in children who are taking this drug. See also Warning.

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Also, babies born to mothers who have used this drug during the last 3 months of pregnancy may infrequently develop withdrawal symptoms such as feeding/breathing difficulties, seizures, muscle stiffness, or constant crying. If you notice any of these symptoms in your newborn, tell the doctor promptly.

Since untreated mental/mood problems (such as depression, anxiety) can be a serious condition, do not stop taking this medication unless directed by your doctor. If you are planning pregnancy, become pregnant, or think you may be pregnant, immediately discuss the benefits and risks of using this medication during pregnancy with your doctor.

This drug passes into breast milk and may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: other drugs that can cause bleeding/bruising (including antiplatelet drugs such as clopidogrel, NSAIDs such as ibuprofen, "blood thinners" such as warfarin).

Other medications can affect the removal of duloxetine from your body, which may affect how duloxetine works. Examples include cimetidine, certain quinolone antibiotics (such as ciprofloxacin, enoxacin), among others.

This medication can slow down the removal of other medications from your body, which may affect how they work. Examples of affected drugs include antiarrhythmic drugs (such as propafenone, flecainide, quinidine), antipsychotics (such as thioridazine), tricyclic antidepressants (such as desipramine, imipramine), among others.

Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO

inhibitors (isocarboxazid, linezolid, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before and at least 5 days after treatment with this medication. Ask your doctor when to start or stop taking this medication.

The risk of serotonin syndrome/toxicity increases if you are also taking other drugs that increase serotonin. Examples include street drugs such as MDMA/"ecstasy," St. John's wort, certain antidepressants (including SSRIs such as fluoxetine/paroxetine, other SNRIs such as desvenlafaxine/venlafaxine), tryptophan, among others. The risk of serotonin syndrome/toxicity may be more likely when you start or increase the dose of these drugs.

Tell your doctor or pharmacist if you are taking other products that cause drowsiness including alcohol, antihistamines (such as cetirizine, diphenhydramine), drugs for sleep or anxiety (such as alprazolam, diazepam, zolpidem), muscle relaxants, and narcotic pain relievers (such as codeine). Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

Aspirin can increase the risk of bleeding when used with this medication. However, if your doctor has directed you to take low-dose aspirin for heart attack or stroke prevention (usually at dosages of 81-325 milligrams a day), you should continue taking it unless your doctor instructs you otherwise.

OVERDOSE:

If overdose is suspected, contact a poison control center or emergency room immediately. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: severe drowsiness, fainting.

NOTES:

Do not share this medication with others.

Keep all regular medical and psychiatric appointments. Laboratory and/or medical tests (such as blood pressure, liver function) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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