

DULOXETINE (CYMBALTA)

Duloxetine (Cymbalta) is approved by the FDA for treatment of major depressive disorder; management of pain associated with diabetic neuropathy. It is useful in treating chronic neuropathic pain from other causes.

Duloxetine comes in 30 and 60 mg tablets. The standard dose is 60 mg per day. To be certain you can tolerate the medication, the starting dose is 30 mg daily. You should stay at that dose for 14 days before increasing. It is possible but unlikely that you will get any benefit from this low dose.

If you do not have problems with side-effects, increase the dose to 60 mg once a day. Duloxetine can be taken any time of the day with or without a meal.

At 60 mg per day, you should know within 30 days if the medication is going to help.

You should NOT take Duloxetine if:

You are allergic to duloxetine hydrochloride or other ingredients in it.

You currently or have recently taken monoamine oxidase inhibitor (MAOI).

You have uncontrolled narrow-angle glaucoma.

You are taking Mellaril® (thioridazine).

The most common side effect when taking duloxetine was nausea. For most people, the nausea was mild to moderate, and usually subsided within one to two weeks. Other common side effects included (listed in order of frequency): Constipation, Decreased appetite, Dizziness, Dry mouth, Fatigue, Increased sweating, Loss of strength or energy, Sleepiness.

Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. In clinical studies, some people taking duloxetine experienced an increase in blood pressure. Your doctor may periodically check your blood pressure while you are taking duloxetine.

No blood monitoring is needed when taking duloxetine.

More information can be found at www.cymbalta.com.

DULOXETINE (By mouth)
Duloxetine (doo-LOX-e-teen)

Treats depression. Also treats nerve pain caused by diabetes. This medicine is a selective serotonin and norepinephrine reuptake inhibitor (SSNRI).

Brand Name(s): Cymbalta

There may be other brand names for this medicine.

When This Medicine Should Not Be Used:

You should not use this medicine if you have had an allergic reaction to duloxetine, or if you have used an MAO inhibitor (MAOI) such as Eldepryl®, Marplan®, Nardil®, or Parnate® within the past 14 days. You should not use this medicine if you have uncontrolled narrow-angle glaucoma.

How to Use This Medicine:

Delayed Release Capsule

- Your doctor will tell you how much of this medicine to use and how often. Your dose may need to be changed several times in order to find out what works best for you. Do not use more medicine or use it more often than your doctor tells you to.
- You may take this medicine with or without food.
- Swallow the **delayed-release capsule** whole. Do not sprinkle contents of the capsule on food or mix with liquids before you take it. Do not crush, break, open, or chew it.
- You may need to use this medicine for several weeks before you begin to feel better. Keep using the medicine even if you feel your condition is not improving.
- This medicine should come with a Medication Guide. Read and follow these instructions carefully. Ask your doctor or pharmacist if you have any questions. Ask your pharmacist for the Medication Guide if you do not have one. Your doctor might ask you to sign some forms to show that you understand this information.

If a dose is missed:

- If you miss a dose or forget to use your medicine, use it as soon as you can. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not use extra medicine to make up for a missed dose.

How to Store and Dispose of This Medicine:

- Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light.
- Ask your pharmacist, doctor, or health caregiver about the best way to dispose of any leftover medicine after you have finished your treatment. You will also need to throw away old medicine after the expiration date has passed.
- Keep all medicine away from children and never share your medicine with anyone.

Drugs and Foods to Avoid:

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

- Make sure your doctor knows if you are using St. John's Wort, lithium (Lithane®, Lithobid®, Eskalith®), tramadol (Ultram®), other medicines to treat depression (such as amitriptyline, desipramine, fluoxetine, fluvoxamine, imipramine, nortriptyline, paroxetine, Celexa®, Effexor®, Lexapro™, Luvox®, Norpramin®, Paxil®, Zoloft®), medicine to treat headaches (such as eletriptan, sumatriptan, Imitrex®, Relpax®), medicine to treat an infection (such as linezolid, Ciloxan®,

Cipro®, Levaquin®, Tequin®, Zyvox®), phenothiazine medicine (such as prochlorperazine, thioridazine, Compazine®, Mellaril®, Phenergan®, Thorazine®, Trilafon®), or medicine for heart rhythm problems (such as flecainide, propafenone, quinidine, Rythmol®, Tambocor®).

- Tell your doctor if you are using any medicines that make you sleepy. These include sleeping pills, cold and allergy medicine, narcotic pain relievers, and sedatives.
- Do not drink alcohol while you are using this medicine. Drinking alcohol while using this medicine may increase your risk of liver damage. If you regularly drink 3 or more alcoholic drinks every day, tell your doctor.

Warnings While Using This Medicine:

- Make sure your doctor knows if you are pregnant, trying to become pregnant, or breastfeeding. Tell your doctor if you have heart disease, high blood pressure, narrow-angle glaucoma, kidney disease, liver disease, diabetes, or any digestion problems. Also tell your doctor if you have a history of seizures or mania.
- For some children and teenagers, this medicine can increase thoughts of suicide. All of the warnings in this leaflet are true for a child or teenager who is using this medicine. Tell your doctor right away if you start to feel more depressed. Also tell your doctor right away if you have thoughts about hurting yourself. Report any unusual thoughts or behaviors that trouble you, especially if they are new or get worse quickly. Make sure your caregiver knows if you have trouble sleeping, get upset easily, have a big increase in energy, or start to act reckless. Also tell your doctor if you have sudden or strong feelings, such as feeling nervous, angry, restless, violent, or scared. Let your doctor know if you or anyone in your family has bipolar disorder (manic-depressive) or has tried to commit suicide.
- Make sure your doctor knows if you have ever abused drugs or alcohol.
- This medicine may make you dizzy or drowsy. Avoid driving, using machines, or doing anything else that could be dangerous if you are not alert.
- Your doctor will need to check your progress at regular visits while you are using this medicine. Be sure to keep all appointments.
- Do not stop using this medicine suddenly without asking your doctor. You may need to slowly decrease your dose before stopping it completely.
- After you stop using the medicine, call your doctor if you have mood or behavior changes, confusion, headache, nausea, vomiting, seizures, tingling pain, or ringing in your ears.

Possible Side Effects While Using This Medicine:

Call your doctor right away if you notice any of these side effects:

- Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing.
- Aggression, anxiety, anger, or hostility.
- Dark-colored urine or pale stools.
- Extreme sleepiness or drowsiness.
- Fast or uneven heartbeat, dizziness.
- Feeling confused, nervous, restless, clumsy.
- Muscle spasms, twitching, or stiffness.
- Nausea, vomiting, loss of appetite, pain in your stomach.
- Panic attacks, tremors, or feeling irritable.
- Severe nausea, diarrhea.
- Unexplained fever, sweating, shivering.
- Unusual behavior, or thoughts about hurting yourself.
- Unusual bleeding or bruising.
- Unusual tiredness or weakness.

- Yellowing of your skin or the whites of your eyes.

If you notice these less serious side effects, talk with your doctor:

- Blurred vision.
- Cough, sore throat, runny or stuffy nose.
- Dry mouth, constipation, upset stomach, mild nausea or diarrhea.
- Feeling tired, or having trouble sleeping.
- Headache.
- Increased sweating.
- Problems with sex, loss of interest in sex.
- Problems with urination.
- Skin rash.
- Weight loss.

If you notice other side effects that you think are caused by this medicine, tell your doctor.

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