

Medication Guide

Duloxetine Delayed-Release Capsules (doo-LOX-e-teen)

Read this Medication Guide before you start taking duloxetine delayed-release capsules and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Talk to your healthcare provider about:

- all risks and benefits of treatment with antidepressant medicines
- all treatment choices for depression or other serious mental illness

What is the most important information I should know about antidepressant medicines, depression, other serious mental illnesses, and suicidal thoughts or actions?

1. **Duloxetine delayed-release capsules and other antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment or when the dose is changed.**
2. **Depression and other serious mental illnesses are the most important causes of suicidal thoughts or actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness).
3. **How can I watch for and try to prevent suicidal thoughts and actions?**
 - Pay close attention to any changes in mood, behavior, actions, thoughts, or feelings, especially sudden changes. This is very important when an antidepressant medicine is started or when the dose is changed.
 - Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call your healthcare provider right away if you have any of the following symptoms or feelings, especially if they are new, worse, or worry you. In an emergency, call 911.

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive, being angry, or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety
- panic attacks
- feeling very agitated or restless
- new or worse irritability
- trouble sleeping
- an extreme increase in activity or talking (mania)
- other unusual changes in behavior or mood

What else do I need to know about antidepressant medicines?

- Never stop an antidepressant medicine without first talking to a healthcare provider. Stopping an antidepressant medicine suddenly can cause other symptoms.
- Antidepressants are medicines used to treat depression and other illnesses. It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients should discuss all treatment choices with your

healthcare provider, not just the use of antidepressants.

- Antidepressant medicines have other side effects. Talk to your healthcare provider about the side effects of the medicine prescribed for you or your family member.
- Antidepressant medicines can interact with other medicines. Know all of the medicines that you or your family member takes. Keep a list of all medicines to show your healthcare provider. Do not start new medicines without first checking with your healthcare provider.

What is Duloxetine Delayed-Release Capsules?

Duloxetine delayed-release capsules are a prescription medicine used to treat a certain type of depression called Major Depressive Disorder (MDD). Duloxetine delayed-release capsules belongs to a class of medicines known as SNRIs (or serotonin-norepinephrine reuptake inhibitors).

- Duloxetine delayed-release capsules is also used to treat or manage:
- Generalized Anxiety Disorder (GAD)
- Diabetic Peripheral Neuropathic Pain (DPNP)
- Fibromyalgia (FM)
- Chronic Musculoskeletal Pain

Who should not take duloxetine delayed-release capsules? Do Not take duloxetine delayed-release capsules if you:

- **take a Monoamine Oxidase Inhibitor (MAOI).** Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid or intravenous methylene blue.
- Do not take an MAOI within 5 days of stopping duloxetine delayed-release capsules unless directed to do so by your healthcare provider.
- Do not start duloxetine delayed-release capsules if you stopped taking an MAOI in the last 14 days unless directed to do so by your healthcare provider.

People who take duloxetine delayed-release capsules close in time to an MAOI may have a serious problem called Serotonin Syndrome (see “What are the possible side effects of duloxetine delayed-release capsules?”).

What should I tell my healthcare provider before taking duloxetine delayed-release capsules?

Before starting duloxetine delayed-release capsules, tell your healthcare provider if you:

- have heart problems or high blood pressure
- have diabetes (duloxetine delayed-release capsules treatment makes it harder for some people with diabetes to control their blood sugar)
- have liver problems
- have kidney problems
- have glaucoma
- have or had seizures or convulsions
- have bipolar disorder or mania
- have low sodium levels in your blood
- have delayed stomach emptying
- have or had bleeding problems

- are pregnant or plan to become pregnant. Duloxetine delayed release capsules may harm your unborn baby. Talk to your healthcare provider about the risk to your unborn baby if you take duloxetine delayed release capsules during pregnancy.
- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with duloxetine delayed release capsules.
- There is a pregnancy registry for females who are exposed to duloxetine delayed-release capsules during pregnancy. The purpose of the registry is to collect information about the health of females exposed to duloxetine delayed-

release capsules and their baby. If you become pregnant during treatment with duloxetine delayed-release capsules, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/research/pregnancyregistry/>.

- are breastfeeding or plan to breastfeed. Duloxetine passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby while taking duloxetine delayed-release capsules.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Duloxetine delayed-release capsules and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Especially tell your healthcare provider if you take:

- triptans used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, buspirone, SSRIs, SNRIs or MAOIs
- tramadol, fentanyl, meperidine, methadone, or other opioids
- amphetamines
- cimetidine
- the antibiotics ciprofloxacin, enoxacin
- medicine to treat irregular heart rate (like propafenone, flecainide, quinidine)
- theophylline
- the blood thinner warfarin (Coumadin, Jantoven)
- non-steroidal anti-inflammatory drug (NSAID)(like ibuprofen, naproxen or aspirin).
- over-the-counter supplements such as tryptophan or St. John's Wort
- thioridazine (Mellaril). Mellaril together with duloxetine delayed-release capsules can cause serious heart rhythm problems or sudden death.

Ask your healthcare provider for a list of these medicines if you are not sure.

Do not take duloxetine delayed-release capsules with any other medicine that contain duloxetine.

How should I take duloxetine delayed-release capsules?

- Take duloxetine delayed-release capsules exactly as your healthcare provider tells you to take it. Your healthcare provider may need to change the dose of duloxetine delayed-release capsules until it is the right dose for you.
- Swallow duloxetine delayed-release capsules whole. Do not chew or crush duloxetine delayed-release capsules.
- Do not open the capsule and sprinkle on food or mix with liquids. Opening the capsule may affect how well duloxetine delayed-release capsules works.
- Duloxetine delayed-release capsules may be taken with or without food.
- If you miss a dose of duloxetine delayed-release capsules, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of duloxetine delayed-release capsules at the same time.
- If you take too much duloxetine delayed-release capsules, call your healthcare provider or poison control center at 1800-222-1222 right away, or get emergency treatment.
- When switching from another antidepressant to duloxetine delayed-release capsules your healthcare provider may want to lower the dose of the initial antidepressant first to potentially avoid side effects.

What should I avoid while taking duloxetine delayed-release capsules?

- Duloxetine delayed-release capsules can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how

