

MEDICATION GUIDE
DULOXETINE (doo lox e teen)
DELAYED-RELEASE CAPSULES, for oral use

What is the most important information I should know about Duloxetine Delayed-Release Capsules?

Duloxetine Delayed-Release Capsules may cause serious side effects, including:

- **Increased risk of suicidal thoughts and actions.** Duloxetine Delayed-Release Capsules and other antidepressant medicines increase the risk of suicidal thoughts and actions in people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed.**
 - **Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.**

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes, in mood, behavior, actions, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Tell your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings or if you develop suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Tell your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Tell your healthcare provider or get emergency help right away if you or your family member taking Duloxetine Delayed-Release Capsules have any of the following symptoms, especially if they are new, worse, or worry you:

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| ▪ suicide attempts | ▪ thoughts about suicide or dying |
| ▪ acting aggressive, being angry, or violent | ▪ acting on dangerous impulses |
| ▪ 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 |

See **“What are the possible side effects of Duloxetine Delayed-Release Capsules?”** for more information about side effects.

What are 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) in adults
- generalized anxiety disorder (GAD) in adults and children 7 years of age and older

It is not known if Duloxetine Delayed-Release Capsules are safe and effective for use in children under 7 years of age with GAD.

It is not known if Duloxetine Delayed-Release Capsules are safe and effective for use in children with MDD or other health conditions.

Who should not take Duloxetine Delayed-Release Capsules?

Do not take Duloxetine Delayed-Release Capsules if you are taking, or have stopped taking within the last 14 days, a medicine called a Monoamine Oxidase Inhibitor (MAOI) including the antibiotic linezolid or intravenous methylene blue.

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 start taking an MAOI for at least 5 days after you stop treatment with Duloxetine Delayed-Release Capsules.

Before taking Duloxetine Delayed-Release Capsules tell your healthcare provider about all your medical conditions, including if you:

- have, or have a family history of suicide, bipolar disorder, depression, mania or hypomania
- have liver or kidney problems
- drink alcohol
- have or had bleeding problems
- have glaucoma (high pressure in the eye)
- have or had seizures (convulsions)
- have high or low blood pressure
- have diabetes or high blood sugar
- have or had heart problems
- have low sodium levels in your blood

- have slow stomach emptying
- have problems urinating (hesitation) or emptying your bladder (urinary retention)
- are pregnant or plan to become pregnant. Duloxetine Delayed-Release Capsules may harm your unborn baby. Taking Duloxetine Delayed-Release Capsules during the third trimester of pregnancy may cause you to have an increased risk of bleeding after your delivery and may also cause the baby to be at increased risk for discontinuation symptoms, or breathing, temperature control, feeding or other problems at birth. Talk to your healthcare provider about the risks to you and your 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 exposure registry for women who are exposed to Duloxetine Delayed-Release Capsules during pregnancy. The purpose of the registry is to collect information about the health of women exposed to Duloxetine Delayed-Release Capsules and their babies. If you become pregnant during treatment with Duloxetine Delayed-Release Capsules, talk to your healthcare provider about registering you with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185 or by visiting online at <https://womensmentalhealth.org/research/pregnancyregistry/antidepressants>
- 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 during treatment with Duloxetine Delayed-Release Capsules.
 - If you breastfeed during treatment with Duloxetine Delayed-Release Capsules, tell your healthcare provider if your baby develops unusual sleepiness or fussiness, or is not feeding well or gaining weight.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Duloxetine Delayed-Release Capsules and other medicines may affect each other causing possible serious side effects. Duloxetine Delayed-Release Capsules may affect the way other medicines work and other medicines may affect the way Duloxetine Delayed-Release Capsules work.

Especially tell your healthcare provider if you take:

- medicines that can increase your risk for developing a serious problem called serotonin syndrome, including:
 - medicines to treat migraine headaches known as triptans
 - medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs), MAOIs, tricyclic antidepressants, lithium, and buspirone
 - tramadol, fentanyl, meperidine, methadone, or other opioids
 - amphetamines
 - tryptophan
 - St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin, or other blood thinners
- diuretics

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take Duloxetine Delayed-Release Capsules with your other medicines.

Do not start or stop any other medicines during treatment with Duloxetine Delayed-Release Capsules without talking to your healthcare provider first. Stopping Duloxetine Delayed-Release Capsules suddenly may cause you to have serious side effects.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

See “What are the possible side effects of Duloxetine Delayed-Release Capsules?”

How should I take Duloxetine Delayed-Release Capsules?

- Take Duloxetine Delayed-Release Capsules exactly as your healthcare provider tells you to. Do not change your dose or stop taking Duloxetine Delayed-Release Capsules without talking to your healthcare provider.
- Your healthcare provider may need to change the dose of Duloxetine Delayed-Release Capsules until it is the right dose for you.
- Your healthcare provider will use a different duloxetine delayed-release capsule medicine when you first start duloxetine treatment, if your dose is changed, if your dose is below 80 mg each day, or if treatment with Duloxetine Delayed-Release Capsules is stopped.
- Take Duloxetine Delayed-Release Capsules 1 time each day on an empty stomach at least 1 hour before or 2 hours after a meal.
- Swallow Duloxetine Delayed-Release Capsules whole.
- **Do not** chew, crush, or open the capsule.

- **Do not** open the capsule and sprinkle on food or mix with liquids. Opening the capsule may affect the way Duloxetine Delayed-Release Capsules work.
- 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 2 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 Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while taking Duloxetine Delayed-Release Capsules?

- **Do not** drive, operate heavy machinery, or do other dangerous activities until you know how Duloxetine Delayed-Release Capsules affect you. Duloxetine Delayed-Release Capsules can make you drowsy, and dizzy.
- **Do not** drink alcohol during treatment with Duloxetine Delayed-Release Capsules. Drinking alcohol during treatment with Duloxetine Delayed-Release Capsules can increase your risk of having severe liver problems.

What are the possible side effects of Duloxetine Delayed-Release Capsules?

Duloxetine Delayed-Release Capsules may cause serious side effects, including:

- See **“What is the most important information I should know about Duloxetine Delayed-Release Capsules?”**
- **Liver problems.** Duloxetine Delayed-Release Capsules may cause severe liver problems that can cause death. Talk to your healthcare provider about how much alcohol you drink. Tell your healthcare provider right away if you develop any of the following symptoms:
 - itching
 - pain in the upper right part of your stomach
 - dark urine
 - your skin or white part of your eyes turn yellow
- **Decreased blood pressure (orthostatic hypotension), falls, and fainting.** You may feel dizzy, lightheaded, or pass out (faint) when you rise too quickly from a sitting or lying position, especially when you start or restart treatment or when the dose is changed, or if you take blood pressure or certain medicines. This may increase your risk for falls or fainting that can cause fractures or other injuries.
- **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take Duloxetine Delayed-Release Capsules with certain other medicines. See, **“Who should not take Duloxetine Delayed-Release Capsules?”** and **“Especially tell your healthcare provider if you take:”** Tell your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following signs and symptoms:
 - agitation
 - confusion
 - fast heartbeat
 - dizziness
 - flushing
 - tremors, stiff muscles, or muscle twitching
 - seizures
 - seeing or hearing things that are not real (hallucinations)
 - coma
 - changes in blood pressure
 - sweating
 - high body temperature (hyperthermia)
 - loss of coordination
 - nausea, vomiting, diarrhea
- **Increased risk of bleeding.** Taking Duloxetine Delayed-Release Capsules with aspirin, non-steroidal anti-inflammatory drugs (NSAIDs), or blood thinners may add to this risk. Tell your healthcare provider about any unusual bleeding or bruising.
- **Severe skin reactions.** Duloxetine Delayed-Release Capsules may cause severe skin reactions that may need to be treated in a hospital and may be life-threatening. Stop taking Duloxetine Delayed-Release Capsules and tell your healthcare provider or get emergency help right away if you develop skin blisters, peeling rash, sores in the mouth, hives or any other allergic reactions during treatment with Duloxetine Delayed-Release Capsules.
- **Discontinuation syndrome.** Suddenly stopping Duloxetine Delayed-Release Capsules may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:
 - dizziness
 - irritability and agitation
 - anxiety
 - sweating
 - seizures
 - ringing in your ears (tinnitus)
 - nausea
 - problems sleeping
 - tiredness
 - confusion
 - electric shock sensation (paresthesia)
 - headache
 - diarrhea
 - abnormal dreams
 - changes in your mood
 - hypomania
- **Manic episodes.** Tell your healthcare provider if you develop any signs and symptoms of manic reactions, including:
 - greatly increased energy
 - racing thoughts
 - unusually grand ideas
 - talking more or faster than usual
 - severe trouble sleeping
 - reckless behavior
 - excessive happiness or irritability
- **Eye problems (angle-closure glaucoma).** Duloxetine Delayed-Release Capsules may cause a type of eye problem called angle-closure glaucoma in people with certain other eye conditions. You may want to undergo an

eye examination to see if you are at risk and receive preventative treatment if you are. Tell your healthcare provider if you develop eye pain, changes in your vision, or swelling or redness in or around the eye.

- **Seizures (convulsions).**
- **Increases in blood pressure.** Your healthcare provider should check your blood pressure before you start and during treatment with Duloxetine Delayed-Release Capsules. If you have high blood pressure, it should be controlled before you start treatment with Duloxetine Delayed-Release Capsules.
- **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood may be severe and may cause death. Elderly people and people who take diuretics or who become dehydrated may be at greater risk for this. Tell your healthcare provider if you develop signs and symptoms of hyponatremia, which may include:
 - headache
 - difficulty concentrating
 - memory problems
 - confusion
 - weakness or unsteadiness on your feet which can lead to falls

In severe or more sudden cases, signs and symptoms include:

- hallucinations (seeing or hearing things that are not real)
- fainting
- seizures
- coma
- stopping breathing (respiratory arrest)
- **Problems with urination.** Duloxetine Delayed-Release Capsules may cause you to have problems with urination including decreased urine flow or being unable to pass any urine. Tell your healthcare provider if you develop any problems with urine flow during treatment with Duloxetine Delayed-Release Capsules.
- **Sexual problems (dysfunction).** Taking Duloxetine Delayed-Release Capsules may cause sexual problems. Symptoms in males may include:
 - delayed ejaculation or inability to have an ejaculation
 - decreased sex drive
 - problems getting or keeping an erectionSymptoms in females may include:
 - decreased sex drive
 - delayed orgasm or inability to have an orgasm

Talk to your healthcare provider if you develop any changes in your sexual function or if you have any questions or concerns about sexual problems during treatment with Duloxetine Delayed-Release Capsules. There may be treatments your healthcare provider can suggest.

The most common side effects of Duloxetine Delayed-Release Capsules in adults include:

- nausea
- dry mouth
- sleepiness
- constipation
- decreased appetite
- increased sweating

The most common side effects of Duloxetine Delayed-Release Capsules in children include:

- decreased weight
- decreased appetite
- nausea
- vomiting
- tiredness
- diarrhea

Height and weight changes in children may happen during treatment with Duloxetine Delayed-Release Capsules. Your child's height and weight should be checked during treatment with Duloxetine Delayed-Release Capsules.

These are not all the possible side effects of Duloxetine Delayed-Release Capsules.

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

How should I store Duloxetine Delayed-Release Capsules?

- Store Duloxetine Delayed-Release Capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- Duloxetine Delayed-Release Capsules come in a container with a child resistant cap.

Keep Duloxetine Delayed-Release Capsules and all medicines out of the reach of children.

General information about the safe and effective use of Duloxetine Delayed-Release Capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Duloxetine Delayed-Release Capsules for a condition for which it was not prescribed. Do not give Duloxetine Delayed-Release Capsules to other people, even if they have the same symptoms that you have. It may harm them. You may ask your pharmacist or healthcare provider for information about Duloxetine Delayed-Release Capsules that is written for health professionals.

What are the ingredients in Duloxetine Delayed-Release Capsules?

Active ingredient: duloxetine hydrochloride

Inactive ingredients: Pellets: colloidal silicon dioxide, cysteine, hypromellose, hypromellose phthalate, sucrose, sugar spheres, talc, and triethyl citrate. **Capsule shells:** 80 mg D&C Yellow #10, gelatin, and titanium dioxide. 90 mg D&C Yellow #10, FD&C Blue #1, FD&C Red #40, gelatin, and titanium dioxide. 120 mg D&C Yellow #10, FD&C Green #3, FD&C Red #40, gelatin, and titanium dioxide.

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For more information about Duloxetine Delayed-Release Capsules, call 1-877-447-7979.

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