

Medication Guide

Duloxetine (doo-LOX-e-teen)

Delayed-Release Capsules, USP

Rx Only

Read the Medication Guide that comes with duloxetine delayed-release before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk with your healthcare provider if there is something you do not understand or want to learn more about.

What is the most important information I should know about duloxetine delayed-release capsules?

Duloxetine delayed-release and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **Duloxetine delayed-release 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**.
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts actions.
- Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when duloxetine delayed-release is started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

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

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency. Duloxetine delayed-release may be associated with these serious side effects:

2. Liver damage- symptoms may include:

- itching
- right upper abdominal pain
- dark urine
- hepatitis with yellow skin or eyes
- enlarged liver
- increased liver enzymes

3. Serotonin Syndrome -This condition can be life-threatening and may include:

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity
- dizziness
- flushing
- tremor
- seizures

4. Abnormal bleeding: Duloxetine delayed-release and other antidepressant medicines may increase your risk of bleeding or bruising, especially if you take the blood thinner warfarin (Coumadin*, Jantoven*), a non-steroidal anti-inflammatory drug (NSAIDs, like ibuprofen or naproxen), or aspirin.

5. Severe skin reactions: Duloxetine delayed-release may cause serious skin reactions that may require stopping its use. This may need to be treated in a hospital and may be life-threatening. Call your doctor right away or get emergency help if you have skin blisters, peeling rash, sores in the mouth, hives or any other allergic reactions.

6. Manic episodes:

- greatly increased energy
- severe trouble sleeping
- racing thoughts
- reckless behavior
- unusually grand ideas
- excessive happiness or irritability
- talking more or faster than usual

7. Seizures or convulsions

8. Changes in blood pressure. Monitor your blood pressure before starting and throughout treatment.

Duloxetine delayed-release may:

- increase your blood pressure.
- decrease your blood pressure when standing and cause dizziness or fainting, mostly when first starting duloxetine delayed-release or when increasing the dose.

9. Low salt (sodium) levels in the blood. Elderly people may be at greater risk for this.

Symptoms may include:

- headache
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

10. Problems with urination include:

- decreased urine flow
- unable to pass any urine

11. Changes in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

Do not stop duloxetine delayed-release without first talking to your healthcare provider. Stopping duloxetine delayed-release too quickly or changing from another antidepressant too quickly may result in serious symptoms including:

- anxiety, irritability
- feeling tired or problems sleeping
- headache, sweating, dizziness
- electric shock-like sensations
- vomiting, nausea, diarrhea

What are duloxetine delayed-release capsules?

Duloxetine delayed-release is a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider.

Duloxetine delayed-release is also used to treat or manage:

- Major Depressive Disorder (MDD)
- Generalized Anxiety Disorder (GAD)
- Diabetic Peripheral Neuropathic Pain (DPNP)
- Fibromyalgia (FM)

Talk to your healthcare provider if you do not think that your condition is getting better with duloxetine delayed-release treatment.

Who should not take duloxetine delayed-release capsules?

Do NOT take duloxetine delayed-release if you:

- have uncontrolled narrow-angle glaucoma
- 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.
- Do not take an MAOI within 5 days of stopping duloxetine delayed-release unless directed to do so by your physician.

Do not start duloxetine delayed-release if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your physician.

People who take duloxetine delayed-release close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- high fever
- uncontrolled muscle spasms
- stiff muscles
- rapid changes in heart rate or blood pressure
- confusion
- loss of consciousness (pass out)
- **take Mellaril* (thioridazine) because this can cause serious heart rhythm problems or sudden death**

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

Ask if you are not sure.

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

- Are taking certain drugs such as:
- 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 and fentanyl
- Cimetidine
- The antibiotics ciprofloxacin, enoxacin
- Medicine to control heart rate such as 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
- have heart problems or high blood pressure
- have diabetes (duloxetine delayed-release treatment worsens the control of blood sugar in some patients with diabetes)
- 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. It is not known if duloxetine delayed-release will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression or other conditions with duloxetine delayed-release during pregnancy.
- are breast-feeding or plan to breast-feed. Some duloxetine may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking duloxetine delayed-release.

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

Your healthcare provider or pharmacist can tell you if it is safe to take duloxetine delayed-release with your other medicines. Do not start or stop any medicine while taking duloxetine delayed-release without talking to your healthcare provider first.

If you take duloxetine delayed-release capsules, you should not take any other medicines that contain duloxetine.

How should I take duloxetine delayed-release capsules?

- Take duloxetine delayed-release exactly as prescribed. Your healthcare provider may need to change the dose of duloxetine delayed-release until it is the right dose for you.
- Do not open, break or chew the capsule; it must be swallowed whole.
- Duloxetine delayed-release capsules may be taken with or without food.
- If you miss a dose of duloxetine delayed-release, 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 at the same time.
- If you take too many duloxetine delayed-release capsules, call your healthcare provider or poison control center right away, or get emergency treatment.
- When switching from another antidepressant to duloxetine delayed-release your doctor 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 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 duloxetine delayed-release affects you.
- Use of duloxetine delayed-release concomitantly with heavy alcohol intake may be associated with severe liver injury. Avoid heavy alcohol use while taking duloxetine delayed-release.

What are the possible side effects of duloxetine delayed-release capsules?

Duloxetine delayed-release may cause serious side effects, including all of those described in the section entitled “**What is the most important information I should know about duloxetine delayed-release capsules?**”

Common possible side effects in people who take duloxetine delayed-release include:

- nausea
- dry mouth
- sleepiness
- fatigue
- loss of appetite
- increased sweating
- dizziness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of duloxetine delayed-release. For more information, ask your healthcare provider or pharmacist.

CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS. YOU MAY REPORT SIDE EFFECTS TO THE FDA AT 1-800-FDA-1088.

How should I store duloxetine delayed-release capsules?

Store duloxetine delayed-release capsules at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Keep duloxetine delayed-release and all medicines out of the reach of children.

General information about duloxetine delayed-release capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use duloxetine delayed-release for a condition for which it was not prescribed. Do not give duloxetine delayed-release to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about duloxetine delayed-release. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about duloxetine delayed-release that is written for healthcare professionals.

For more information about duloxetine delayed-release call AvKARE, Inc. 1-855-361-3993.

What are the ingredients in duloxetine delayed-release capsules, USP?

Active ingredient: duloxetine hydrochloride, USP

Inactive ingredients: ammonium hydroxide, black iron oxide, gelatin, hydroxypropyl cellulose, hydroxypropyl methylcellulose phthalate, hypromellose, potassium hydroxide, propylene glycol, shellac, sugar spheres (sucrose and corn starch), talc, titanium dioxide and triethyl citrate. The 20 mg and 30 mg capsules also contain FD&C Blue # 1 Aluminum Lake.

This Medication Guide has been approved by the U.S. Food and Drug Administration

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Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478
Mfg. Rev. 10/13
AV 07/14 (P)