

MEDICATION GUIDE

Desvenlafaxine (des VEN la FAX een) extended-release tablets

What is the most important information I should know about desvenlafaxine?

Desvenlafaxine can cause serious side effects, including:

o **Increased risk of suicidal thoughts or actions in some children, adolescents and young adults.** Desvenlafaxine and other antidepressant medicines may increase suicidal thoughts and actions in some people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed. Desvenlafaxine is not for use in children.**

- **Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions. Some people may have a higher risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) depression, bipolar illness (also called manic-depressive illness) or have a history of suicidal thoughts or actions.

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

o Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings, or if you develop suicidal thought or actions. This is very important when an antidepressant medicine is started or when the dose is changed.

o Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.

o 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 or get emergency help right away if you or a family member have any of the following symptoms, especially if they are new, worse, or worry you:

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

What is desvenlafaxine?

Desvenlafaxine is a prescription medicine used to treat adults with a certain type of depression called major depressive disorder (MDD).

It is not known if desvenlafaxine is safe and effective for use in children.

Who should not take desvenlafaxine?

Do not take desvenlafaxine if you:

- are allergic to desvenlafaxine succinate, venlafaxine hydrochloride, or any of the ingredients in desvenlafaxine extended-release tablets. See the end of this Medication Guide for a complete list of ingredients in desvenlafaxine.
- take a Monoamine Oxidase Inhibitor (MAOI)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or intravenous methylene blue

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI or one of these medicines, including intravenous methylene blue.

Do not start taking an MAOI for at least 7 days after you stop treatment with desvenlafaxine.

Before taking desvenlafaxine, tell your healthcare provider about all your medical conditions, including if you:

- have or have a family history of suicide, depression, bipolar disorder, mania or hypomania
- have high blood pressure
- have or had heart problems or stroke
- have or had bleeding problems
- have glaucoma (high pressure in the eye)
- have or had seizures (convulsions)
- have low sodium levels in your blood
- have lung or breathing problems
- have high cholesterol or high triglycerides
- have kidney or liver problems
- drink alcohol
- are pregnant or plan to become pregnant. Desvenlafaxine may harm your unborn baby. Taking desvenlafaxine during your pregnancy may cause an increased risk of bleeding after delivery and may cause harm to you or your baby. Talk to your healthcare provider about the risk to your unborn baby if you take desvenlafaxine during pregnancy.

o Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with desvenlafaxine.

o There is a pregnancy registry for females who are exposed to desvenlafaxine during pregnancy. The purpose of the registry is to collect information about the health of females exposed to desvenlafaxine and their baby. If you become pregnant during treatment with desvenlafaxine, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185.

- are breastfeeding or plan to breastfeed. Desvenlafaxine can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with desvenlafaxine.

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

Desvenlafaxine and other medicines may affect each other causing possible serious side effects. Desvenlafaxine may affect the way other medicines work and other medicines may affect the way desvenlafaxine works.

Especially tell your healthcare provider if you take:

- other MAOIs
- medicines to treat migraine headaches known as triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- amphetamines
- St. John's Wort
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), and warfarin
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

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 desvenlafaxine with your other medicines.

Do not start or stop any other medicines during treatment with desvenlafaxine without talking to your healthcare provider first. Stopping desvenlafaxine suddenly may cause you to have serious side effects. See, **“What are the possible side effects of desvenlafaxine?”**

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

How should I take desvenlafaxine?

- Take desvenlafaxine exactly as your healthcare provider tells you to. Do not change your dose or stop taking desvenlafaxine without first talking to your healthcare provider.
- Your healthcare provider may change the dose of desvenlafaxine until it is the right dose for you.
- Take desvenlafaxine 1 time a day at about the same time each day.
- Take desvenlafaxine with or without food.
- Swallow desvenlafaxine tablets whole with fluid. Do not divide, crush, chew, or dissolve desvenlafaxine tablets.
- When you take desvenlafaxine, you may see something in your stool that looks like a tablet. This is the empty shell from the tablet after the medicine has been absorbed by your body.
- If over-exposure occurs, call your Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What should I avoid while taking desvenlafaxine?

- Do not drive a car, operate heavy machinery or do other dangerous activities until you know how desvenlafaxine affects you.
- Avoiding drinking alcohol during treatment with desvenlafaxine.

What are the possible side effects of desvenlafaxine?

Desvenlafaxine can cause serious side effects, including:

- See, **“What is the most important information I should know about desvenlafaxine?”**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take desvenlafaxine with certain other medicines. See, **“Who should not take desvenlafaxine?”** Stop taking desvenlafaxine and call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the following signs and symptoms of serotonin syndrome:

- o agitation
- o confusion
- o fast heart beat
- o dizziness
- o flushing
- o tremors, stiff muscles, or muscle twitching
- o seizures
- o seeing or hearing things that are not real (hallucinations)
- o coma
- o blood pressure changes
- o sweating
- o high body temperature (hyperthermia)
- o loss of coordination
- o nausea, vomiting, diarrhea

• **High blood pressure (hypertension).** Your healthcare provider should check your blood pressure before you start and during treatment with desvenlafaxine. If you have high blood pressure, it should be controlled before you start treatment with desvenlafaxine.

• **Increased risk of bleeding.** Taking desvenlafaxine with aspirin, NSAIDs, warfarin or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.

• **Eye problems (angle closure glaucoma).** Many antidepressant medicines, including desvenlafaxine, may cause a certain type of eye problem called angle closure glaucoma. Call your healthcare provider if you have changes in your vision or eye pain.

• **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take desvenlafaxine. Symptoms may include:

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

• **Discontinuation syndrome.** Suddenly stopping desvenlafaxine may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:

- o nausea
- o irritability and agitation
- o tremor
- o headache
- o hypomania
- o sweating
- o dizziness
- o anxiety
- o tiredness
- o ringing in your ears (tinnitus)
- o changes in your mood
- o electric shock sensation (paresthesia)
- o confusion
- o problems sleeping
- o seizures

• **Seizures (convulsions).**

• **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood may be serious and may cause death. Elderly people may be at greater risk for this. Signs and Symptoms of low sodium levels in your blood may include:

- o headache
- o difficulty concentrating
- o memory changes
- o confusion
- o weakness and unsteadiness on your feet which can lead to falls

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

- o seeing or hearing things that are not real (hallucinations)
- o fainting
- o seizures
- o coma
- o respiratory arrest
- o death

• **Lung problems.** Some people who have taken the medicine venlafaxine, which is the same kind of medicine as the medicine in desvenlafaxine, have had lung problems. Symptoms of lung problems include difficulty breathing, cough, or chest discomfort. Tell your healthcare provider right away if you have any of these symptoms.

The most common side effects of desvenlafaxine include:

- nausea
- problems sleeping
- constipation
- decreased appetite
- sexual function problems
- dizziness
- sweating
- feeling sleepy
- anxiety

These are not all the possible side effects of desvenlafaxine. 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 desvenlafaxine?

- Store desvenlafaxine at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep desvenlafaxine and all medicines out of the reach of children.**

General Information about the safe and effective use of desvenlafaxine

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

What are the ingredients in desvenlafaxine?

Active ingredient: desvenlafaxine

Inactive ingredients:

50 mg tablet: alginic acid, citric acid monohydrate powder, hypromellose, microcrystalline cellulose, povidone, talc, magnesium stearate and film coating, which consist of hypromellose, titanium dioxide, polyethylene glycol, talc, and iron oxide red

100 mg tablet: alginic acid, citric acid monohydrate powder, hypromellose, microcrystalline cellulose, povidone, talc, magnesium stearate and film coating, which consist of hypromellose, titanium dioxide, polyethylene glycol, iron oxide red, and iron oxide black

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