MEDICATION GUIDE
Desvenlafaxine(des VEN la FAX een) Extended-Release Tablets

What is the most important information I should know about desvenlafaxine extended-release tablets?
Desvenlafaxine extended-release tablets can cause serious side effects, including:

- **Increased risk of suicidal thoughts or actions in some children and young adults within the first few months of treatment. Desvenlafaxine extended-release tablets are not for use in children.**
- 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, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with the healthcare provider as scheduled. Call the 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, especially if they are new, worse, or worry you:

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

What are desvenlafaxine extended-release tablets?

- Desvenlafaxine extended-release tablets are a prescription medicine used to treat adults with a certain type of depression called major depressive disorder (MDD). Desvenlafaxine extended-release tablets belongs to a class of medicines known as serotonin and norepinephrine reuptake inhibitors (SNRIs).

Do not take desvenlafaxine extended-release tablets 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 extended-release tablets.
- take a monoamine oxidase inhibitor (MAOI).
- have stopped taking an MAOI in the last 14 days. Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI.
- are being treated with the antibiotic linezolid or the intravenous methylene blue.

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

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

- have high blood pressure
- have heart problems
- have cerebrovascular problems or had a stroke
- have or had bleeding problems
- have, or have a family history of, bipolar disorder, mania or hypomania
- have high cholesterol or high triglycerides
- have or had depression, suicidal thoughts or behavior
- have kidney or liver problems
- have or had seizures or convulsions
- have low sodium levels in your blood
- are pregnant or plan to become pregnant. Talk to your healthcare provider about the risk to your unborn baby if you take desvenlafaxine extended-release tablets during pregnancy.
  - Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with desvenlafaxine extended-release tablets.
  - If you become pregnant during treatment with desvenlafaxine extended-release tablets, 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 extended-release tablets.

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

Desvenlafaxine extended-release tablets and other medicines may affect each other causing possible serious side effects. Desvenlafaxine extended-release tablets may affect the way other medicines work and other medicines may affect the way desvenlafaxine extended-release tablets 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
- other medicines containing desvenlafaxine or venlafaxine
- medicines that can affect blood clotting such as aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), 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 extended-release tablets with your other medicines.

Do not start or stop any other medicines during treatment with desvenlafaxine extended-release tablets without talking to your healthcare provider first.

Stopping desvenlafaxine extended-release tablets suddenly may cause you to have serious side effects. See, "What are the possible side effects of desvenlafaxine extended-release tablets?"

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

How should I take desvenlafaxine extended-release tablets?

- Take desvenlafaxine extended-release tablets exactly as your healthcare provider tells you to.
- Take desvenlafaxine extended-release tablets 1 time a day at about the same time each day.
- Desvenlafaxine extended-release tablets may be taken either with or without food.
- Swallow desvenlafaxine extended-release tablets whole, with fluid. Do not divide, crush, chew, or dissolve desvenlafaxine extended-release tablets.
- When you take desvenlafaxine extended-release tablets, 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 extended-release tablets?

- Do not drive a car or operate heavy machinery until you know how desvenlafaxine extended-release tablets affects you.
- You should not drink alcohol while taking desvenlafaxine extended-release tablets.

What are the possible side effects of desvenlafaxine extended-release tablets?
Desvenlafaxine extended-release tablets can cause serious side effects, including:

- **See, "What is the most important information I should know about desvenlafaxine extended-release tablets?"**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take desvenlafaxine extended-release tablets with certain other medicines. See, "Do not take desvenlafaxine extended-release tablets if you:" 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:
  - agitation
  - confusion
  - fast heart beat
  - 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
- **New or worsened high blood pressure (hypertension).** Your healthcare provider should check your blood pressure before and during treatment with desvenlafaxine extended-release tablets. If you have high blood pressure, it should be controlled before you start treatment with desvenlafaxine extended-release tablets.
- **Increased chance of bleeding or bruising.** Taking desvenlafaxine extended-release tablets with aspirin, NSAIDs, 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 extended-release tablets, 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.
- **Discontinuation syndrome.** Suddenly stopping desvenlafaxine extended-release tablets when you take higher doses may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include the following, some of which can be severe and last for a long time:
  - dizziness
  - irritability and agitation
  - anxiety
  - aggressiveness (including hostility, rage)
  - tremor
  - 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
  - problems with eyesight (such as blurred vision and trouble focusing)
  - increase in blood pressure
- **Seizures (convulsions).**
- **Low sodium levels in your blood (hyponatremia).** Low sodium levels can happen during treatment with desvenlafaxine extended-release tablets. Low sodium levels in your blood may be serious and may cause death. Signs and Symptoms of low sodium levels in your blood may include:
- headache
- difficulty concentrating
- memory changes
- confusion
- weakness and 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
- **Lung problems.** Some people who have taken the medicine venlafaxine which is the same kind of medicine as the medicine in desvenlafaxine extended-release tablets 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.
- **Sexual Problems (dysfunction).** Taking serotonin and norepinephrine reuptake inhibitors (SNRIs), including desvenlafaxine extended-release tablets, 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 erection

Symptoms 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 desvenlafaxine extended-release tablets. There may be treatments your healthcare provider can suggest.

The most common side effects of desvenlafaxine extended-release tablets 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 extended-release tablets.

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 extended-release tablets?

- Store desvenlafaxine extended-release tablets at 20°C to 25°C (68°F to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) *[see USP Controlled Room Temperature]*.
- **Keep desvenlafaxine extended-release tablets and all medicines out of the reach of children.**

General Information about the safe and effective use of desvenlafaxine extended-release tablets

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

What are the ingredients in desvenlafaxine extended-release tablets?

Active ingredient: desvenlafaxine

Inactive ingredients:

- **50 mg tablet:** Hypromellose, microcrystalline cellulose, talc, magnesium stearate, polyvinyl alcohol, polyethylene glycol, titanium dioxide, FD&C Red #40 and FD&C Yellow #6.
- **100 mg tablet:** Hypromellose, microcrystalline cellulose, talc, magnesium stearate, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, iron oxide yellow, iron oxide red and iron oxide black.

Manufactured by:
Rubicon Research Private Limited
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Distributed by:
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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