

MEDICATION GUIDE

KHEDEZLA (key-DEZ-luh) (desvenlafaxine)Extended-release Tablets

Read this Medication Guide before you start taking KHEDEZLA 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.

Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and Suicidal Thoughts or Actions

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 and other serious mental illnesses, and suicidal thoughts or actions?

- **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
- **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and 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) or 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 a 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 | • trouble sleeping (insomnia) |
| • attempts to commit suicide | • new or worse irritability |
| • new or worse depression | • acting aggressive, being angry, or violent |
| • new or worse anxiety | • acting on dangerous impulses |
| • feeling very agitated or restless | • an extreme increase in activity and talking (mania) |
| • panic attacks | • 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 the healthcare provider, not just the use of antidepressants.

- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of this medicine.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you take. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.

What is KHEDEZLA?

- KHEDEZLA is a prescription medicine used to treat depression. KHEDEZLA belongs to a class of medicines known as SNRIs (or serotonin-norepinephrine reuptake inhibitors).

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

Who should not take KHEDEZLA?

Do not take KHEDEZLA if you:

- are allergic to desvenlafaxine, venlafaxine or any of the ingredients in KHEDEZLA. See the end of this Medication Guide for a complete list of ingredients in KHEDEZLA.
- 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 and the intravenous medicine methylene blue.
- have taken an MAOI within 7 days of stopping KHEDEZLA unless directed by your healthcare provider.
- have started KHEDEZLA and if you stopped taking an MAOI in the last 14 days unless directed by your healthcare provider.

What should I tell my healthcare provider before taking KHEDEZLA?

Tell your healthcare provider about all your medical conditions, including if you:

- have high blood pressure
- have heart problems
- have high cholesterol or high triglycerides
- have a history of a stroke
- have or had depression, suicidal thoughts or behavior
- have glaucoma
- have kidney problems
- have liver problems
- have or had bleeding problems
- have or had seizures or convulsions
- have mania or bipolar disorder
- have low sodium levels in your blood
- are pregnant or plan to become pregnant. It is not known if KHEDEZLA will harm your unborn baby.
- are breastfeeding. KHEDEZLA can pass into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take KHEDEZLA.

Serotonin syndrome

Rare, but potentially life-threatening conditions called serotonin syndrome can happen when medicines such as KHEDEZLA are taken with certain other medicines. Serotonin syndrome can cause serious changes in how your brain, muscles, heart and blood vessels, and digestive system work. **Especially tell your healthcare provider if you take the following:**

- medicines to treat migraine headaches known as triptans
- medicines used to treat mood, anxiety, psychotic, or thought disorders, including tricyclics, lithium, selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or other dopamine antagonists, such as metoclopramide
- silbutramine
- tramadol
- St. John's Wort
- MAOIs (including linezolid, an antibiotic and intravenous methylene blue)
- tryptophan supplements

Ask your healthcare provider if you are not sure if you are taking any of these medicines.

Before you take KHEDEZLA with any of these medicines, talk to your healthcare provider about serotonin syndrome. See “What are the possible side effects of KHEDEZLA?”

Do not take KHEDEZLA with other medicines containing venlafaxine or desvenlafaxine.

How should I take KHEDEZLA?

- Take KHEDEZLA exactly as your healthcare provider has told you.
- Take KHEDEZLA at about the same time each day.
- KHEDEZLA may be taken either with or without food.
- Swallow KHEDEZLA tablets whole, with fluid. Do not crush, cut, chew, or dissolve KHEDEZLA tablets because the tablets are time-released.
- When you take KHEDEZLA, 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.
- It is common for antidepressant medicines such as KHEDEZLA to take several weeks before you start to feel better. Do not stop taking KHEDEZLA if you do not feel results right away.
- Do not stop taking or change the dose of KHEDEZLA without talking with your healthcare provider, even if you feel better.
- Talk with your healthcare provider about how long you should use KHEDEZLA. Take KHEDEZLA for as long as your healthcare provider tells you to.
- If you miss a dose of KHEDEZLA, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Do not try to “make up” for the missed dose by taking two doses at the same time.
- Do not take more KHEDEZLA than prescribed by your healthcare provider. If you take more KHEDEZLA than the amount prescribed, contact your healthcare provider right away.
- If you take too much KHEDEZLA, call the Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Switching from other antidepressants

Side effects from discontinuing antidepressant medication have occurred when patients switched from other antidepressants, including venlafaxine, to desvenlafaxine. Your doctor may gradually reduce the dose of your initial antidepressant medication to help to reduce these side effects.

What should I avoid while taking KHEDEZLA?

- Do not drive a car or operate machinery until you know how KHEDEZLA affects you.
- Avoid drinking alcohol while taking KHEDEZLA.

What are the possible side effects of KHEDEZLA?

KHEDEZLA can cause serious side effects, including:

- **See the beginning of this Medication Guide - Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal Thoughts or Actions.**
- **Serotonin syndrome.** See “What should I tell my healthcare provider before taking KHEDEZLA?”

Get medical help right away if you think that you have these syndromes. Signs and symptoms of these syndromes may include one or more of the following:

-
- | | |
|--|------------------------------|
| • restlessness | • increase in blood pressure |
| • hallucinations (seeing and hearing things that are not real) | • diarrhea |
| • loss of coordination | • coma |
| • fast heart beat | • nausea |
| • increased body temperature | • vomiting |
| • muscle stiffness | • confusion |
-

KHEDEZLA may also cause other serious side effects, including:

- **New or worsened high blood pressure (hypertension).** Your healthcare provider should monitor your blood pressure before and while you are taking KHEDEZLA. If you have high blood pressure, it should be controlled before you start taking KHEDEZLA.
- **Abnormal bleeding or bruising.** KHEDEZLA and other SNRIs/SSRIs may cause you to have an increased chance of bleeding. Taking aspirin, NSAIDs (non-steroidal anti-inflammatory drugs), or blood thinners may add to this risk. Tell your healthcare provider right away about any unusual bleeding or bruising.
- **Visual Problems**
 - Eye pain
 - Changes in vision
 - Swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

- **Symptoms when stopping KHEDEZLA (discontinuation symptoms).** Side effects may occur when stopping KHEDEZLA (discontinuation symptoms), especially when therapy is stopped suddenly. Your healthcare provider may want to decrease your dose slowly to help avoid side effects. Some of these side effects may include:

-
- | | |
|-------------|-------------------|
| • dizziness | • anxiety |
| • nausea | • abnormal dreams |
| • headache | • tiredness |

- irritability
- sweating
- sleeping problems (insomnia)
- diarrhea

-
- **Seizures (convulsions)**
 - **Low sodium levels in your blood.** Symptoms of this may include: headache, difficulty concentrating, memory changes, confusion, weakness and unsteadiness on your feet. In severe or more sudden cases, symptoms can include: hallucinations (seeing or hearing things that are not real), fainting, seizures and coma. If not treated, severe low sodium levels could be fatal.
 - **Lung problems.** Some people who have taken the medicine venlafaxine which is the same kind of medicine as the medicine in KHEDEZLA 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.

Common side effects with KHEDEZLA include:

-
- | | |
|----------------|----------------------------------|
| • nausea | • sleepiness |
| • dizziness | • loss of appetite |
| • insomnia | • anxiety |
| • sweating | • decreased sex drive |
| • constipation | • delayed orgasm and ejaculation |
-

These are not all the possible side effects of KHEDEZLA. Tell your healthcare provider about any side effect that bothers you or does not go away.

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 KHEDEZLA?

- Store KHEDEZLA at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not use KHEDEZLA after the expiration date (EXP), which is on the container. The expiration date refers to the last day of that month.
- Keep KHEDEZLA and all medicines out of the reach of children.

General Information about the safe and effective use of KHEDEZLA

Medicines are sometimes used for conditions that are not mentioned in Medication Guides. Do not use KHEDEZLA for a condition for which it was not prescribed. Do not give KHEDEZLA to other people, even if they have the same symptoms that you have. It may harm them.

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

For more information, call 1-800-793-2145.

What are the ingredients in KHEDEZLA?

Active ingredient: desvenlafaxine

Inactive ingredients:

- **50 mg tablet:** citric acid monohydrate, hypromellose, microcrystalline cellulose, talc, magnesium stearate,

colloidal silicon dioxide and film coating, which consist of titanium dioxide, polyethylene glycol, talc, polyvinyl alcohol, and iron oxides

- **100 mg tablet:** citric acid monohydrate, hypromellose, microcrystalline cellulose, colloidal silicon dioxide, talc, magnesium stearate, and film coating, which consist of hypromellose, titanium dioxide, polyethylene glycol, talc, polyvinyl alcohol, iron oxides and FD&C yellow #6

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

Manufactured for:

Osmotica Pharmaceutical US LLC
Marietta, GA 30062

By: Alcami

1726 North 23rd Street,
Wilmington, NC 28405

Distributed by:

Pernix Therapeutics, LLC
Morristown, NJ 07960

Revised 07/2016

MG 374-01-84-03

PC 4623GM