

MEDICATION GUIDE
PRISTIQ® (pris-TEEK)
(desvenlafaxine)
extended-release tablets

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

PRISTIQ 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. PRISTIQ is 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:

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| ○ 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 is PRISTIQ?

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

Do not take PRISTIQ if you:

- are allergic to desvenlafaxine succinate, venlafaxine hydrochloride, or any of the ingredients in PRISTIQ. See the end of this Medication Guide for a complete list of ingredients in PRISTIQ.
- 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 PRISTIQ.

Before taking PRISTIQ 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 PRISTIQ during pregnancy.

- Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with PRISTIQ.
- If you become pregnant during treatment with PRISTIQ, 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. PRISTIQ can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with PRISTIQ.

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

PRISTIQ and other medicines may affect each other causing possible serious side effects. PRISTIQ may affect the way other medicines work and other medicines may affect the way PRISTIQ 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 PRISTIQ with your other medicines.

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

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 PRISTIQ?

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

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

What are the possible side effects of PRISTIQ?

PRISTIQ can cause serious side effects, including:

- **See, What is the most important information I should know about PRISTIQ?"**
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take PRISTIQ with certain other medicines. See, "Who should not take PRISTIQ?" 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:

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| ○ agitation | ○ seeing or hearing things that are not real (hallucinations) |
| ○ confusion | ○ coma |
| ○ fast heart beat | ○ changes in blood pressure |
| ○ dizziness | ○ sweating |
| ○ flushing | ○ high body temperature (hyperthermia) |
| ○ tremors, stiff muscles, or muscle twitching | ○ loss of coordination |
| ○ seizures | ○ nausea, vomiting, diarrhea |
- **New or worsened high blood pressure (hypertension).** Your healthcare provider should check your blood pressure before and during treatment with PRISTIQ. If you have high blood pressure, it should be controlled before you start treatment with PRISTIQ.
 - **Increased chance of bleeding or bruising.** Taking PRISTIQ 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 PRISTIQ, 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 PRISTIQ 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:

○ dizziness	○ nausea	○ headache
○ irritability and agitation	○ problems sleeping	○ diarrhea
○ anxiety	○ tiredness	○ abnormal dreams
○ sweating	○ confusion	○ changes in your mood
○ seizures	○ electric shock sensation	○ hypomania
○ ringing in your ears (tinnitus)	(paresthesia)	

- **Seizures (convulsions).**
- **Low sodium levels in your blood (hyponatremia).** Low sodium levels can happen during treatment with PRISTIQ. 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 PRISTIQ 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 PRISTIQ include:

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

These are not all the possible side effects of PRISTIQ.

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 PRISTIQ?

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

General Information about the safe and effective use of PRISTIQ

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take PRISTIQ for a condition for which it was not prescribed. Do not give PRISTIQ 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 PRISTIQ that is written for healthcare professionals.

What are the ingredients in PRISTIQ?

Active ingredient: desvenlafaxine

Inactive ingredients:

- **25 mg tablet:** hypromellose, microcrystalline cellulose, talc, magnesium stearate, a film coating which consists of polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, and iron oxides.
- **50 mg tablet:** hypromellose, microcrystalline cellulose, talc, magnesium stearate and film coating, which consists of polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, and iron oxides.
- **100 mg tablet:** hypromellose, microcrystalline cellulose, talc, magnesium stearate, a film coating which consists of polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, iron oxide and FD&C yellow #6.



For more information, go to www.pristiq.com or call 1-888-PRISTIQ (774-7847).

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

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