

## MEDICATION GUIDE

PRISTIQ® (pris-TEEK) Extended-Release Tablets

(desvenlafaxine)

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

Read the Medication Guide that comes with your or your family member's antidepressant medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines.

#### **Talk to your, or your family member's, 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?**

1. **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
2. **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.
3. **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
  - 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, or after discontinuation.
  - 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 or your family member has 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           |
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## 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 and their families or other caregivers 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 the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. 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 approved for use in children.** Talk to your child's healthcare provider for more information.

## Important Information about PRISTIQ® Extended-Release Tablets

Read the patient information that comes with PRISTIQ before you take PRISTIQ and each time you refill your prescription. There may be new information. If you have questions, ask your healthcare provider. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

## What is PRISTIQ?

- PRISTIQ is a prescription medicine used to treat depression. PRISTIQ belongs to a class of medicines known as SNRIs (or serotonin-norepinephrine reuptake inhibitors).
- PRISTIQ has not been approved for use in children and adolescents.

## Who should not take PRISTIQ?

### Do not take PRISTIQ if you:

- are allergic to desvenlafaxine, venlafaxine 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 a MAOI in the last 14 days. Ask your healthcare provider or pharmacist if you are not sure if you take a MAOI.
- are being treated with the antibiotic linezolid or the intravenous methylene blue.

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

## What should I tell my healthcare provider before taking PRISTIQ?

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. 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.
- 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.

### **Serotonin syndrome or neuroleptic malignant syndrome (NMS)-like reactions**

Rare, but potentially life-threatening, conditions called serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions can happen when medicines such as PRISTIQ are taken with certain other medicines. Serotonin syndrome or NMS-like reactions 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), antipsychotic drugs, or other dopamine antagonists, such as metoclopramide
- amphetamines
- sibutramine
- opioids (e.g., fentanyl, tramadol)
- St. John's Wort
- MAOIs (including linezolid, an antibiotic)
- tryptophan supplements

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

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

**PRISTIQ contains the medicine desvenlafaxine. Do not take PRISTIQ with other medicines containing venlafaxine or desvenlafaxine.**

## **How should I take PRISTIQ?**

- Take PRISTIQ exactly as your healthcare provider has told you.
- Take PRISTIQ at about the same time each day.
- PRISTIQ may be taken either with or without food.
- Swallow PRISTIQ tablets whole, with fluid. Do not crush, cut, chew, or dissolve PRISTIQ tablets because the tablets are time-released.
- 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.
- It is common for antidepressant medicines such as PRISTIQ to take several weeks before you start to feel better. Do not stop taking PRISTIQ if you do not feel results right away.
- Do not stop taking or change the dose of PRISTIQ without talking with your healthcare provider, even if you feel better.
- Talk with your healthcare provider about how long you should use PRISTIQ. Take PRISTIQ for as long as your healthcare provider tells you to.
- If you miss a dose of PRISTIQ, 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 PRISTIQ than prescribed by your healthcare provider. If you take more PRISTIQ than the amount prescribed, contact your healthcare provider right away.
- In case of an overdose of PRISTIQ, call your healthcare provider or poison control center, or go to the 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 PRISTIQ. 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 PRISTIQ?**

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

## **What are the possible side effects of PRISTIQ?**

### **PRISTIQ 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 or neuroleptic malignant syndrome (NMS)-like reactions.** See “What should I tell my healthcare provider before taking PRISTIQ?”
- **Sexual Problems.** Sexual problems can occur while taking PRISTIQ. In some patients these problems may be long lasting after discontinuation of PRISTIQ.

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:

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• 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

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**PRISTIQ 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 PRISTIQ. If you have high blood pressure, it should be controlled before you start taking PRISTIQ.
- **Abnormal bleeding or bruising.** PRISTIQ 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.
- **Glaucoma (increased eye pressure)**
- **Increased cholesterol and triglyceride levels in your blood**
- **Symptoms when stopping PRISTIQ (discontinuation symptoms).** Side effects may occur when stopping PRISTIQ (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 (in some patients these symptoms can be severe and last for long time):

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• dizziness	• anxiety
• nausea	• abnormal dreams
• headache	• tiredness
• irritability and agitation	• sweating
• sleeping problems (insomnia)	• diarrhea
• aggressiveness	• confusion
• changes in your mood	• seizures
• hypomania	• problems with eyesight
• electric shock sensation (paresthesia)	• increase in blood pressure
• ringing in your ears (tinnitus)	

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- **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.
- **Allergic reactions.** Some reactions can be severe such as swelling beneath the skin (e.g., throat, face, hands).

Contact your healthcare provider if you think you have any of these side effects.

Common side effects with PRISTIQ include:

• nausea	• tiredness
• headache	• diarrhea
• dry mouth	• vomiting
• sweating	• anxiety
• dizziness	• tremor
• insomnia	• dilated pupils
• constipation	• decreased sex drive
• loss of appetite	• delayed orgasm and ejaculation
• sleepiness	• feeling that your surroundings are spinning or moving

These are not all the possible side effects of PRISTIQ. 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.

### How should I store PRISTIQ?

- Store PRISTIQ below 30°C.
- Do not use PRISTIQ after the expiration date (EXP), which is on the container. The expiration date refers to the last day of that month.
- Keep PRISTIQ and all medicines out of the reach of children.

### General information about the safe and effective use of PRISTIQ

Medicines are sometimes used for conditions that are not mentioned in Medication Guides. Do not use 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.

This Medication Guide summarizes the most important information about PRISTIQ. If you would like more information, talk with your healthcare provider. 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:** For the 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.

For the 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.

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