

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrPRISTIQ®

desvenlafaxine extended-release tablets

Read this carefully before you start taking **PRISTIQ** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRISTIQ**.

Serious Warnings and Precautions

New or worsened emotional or behavioural problems:

- When you first start taking PRISTIQ or when your dose is adjusted, you may feel worse instead of better. You may feel new or worsened feelings of agitation, hostility, anxiety, or impulsivity.
- During your treatment with PRISTIQ, it is important that you and your healthcare professional talk regularly about how you are feeling. They will closely monitor you for signs of new or worsened emotions or behaviours while you are taking PRISTIQ.
- You may find it helpful to tell a relative or close friend that you are depressed. Ask them to read this leaflet. You might ask them to tell you if they:
 - think your depression is getting worse, or
 - are worried about changes in your behaviour.
- If your depression worsens or you experience changes in your behaviour, tell your healthcare professional **right away**. Do not stop taking your medicine as it takes time for PRISTIQ to work.

Self-harm or Suicide:

- Antidepressants, such as PRISTIQ, may increase the risk of suicidal thoughts and actions for some patients.
- If you have thoughts of harming or killing yourself at any time, contact your healthcare professional or go to a hospital **right away**. Close observation by a healthcare professional is necessary in this situation.

What is PRISTIQ used for?

PRISTIQ is used in adults to relieve the symptoms of:

- Major depressive disorder (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain)

How does PRISTIQ work?

PRISTIQ belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). PRISTIQ is thought to work by increasing the levels of two chemicals in the brain, serotonin and norepinephrine. This helps to relieve your symptoms of major depressive disorder.

What are the ingredients in PRISTIQ?

Medicinal ingredients: Desvenlafaxine succinate

Non-medicinal ingredients: Film coating (which consists of iron oxides, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, and sunset yellow aluminum lake), hypromellose, magnesium stearate, microcrystalline cellulose, and talc.

PRISTIQ comes in the following dosage forms:

Extended-release tablets: 50 mg and 100 mg desvenlafaxine (as desvenlafaxine succinate).

Do not use PRISTIQ if:

- you are allergic to venlafaxine, desvenlafaxine succinate or to any other ingredients in PRISTIQ.
- you are taking, or have taken in the last 14 days, a monoamine oxidase inhibitor (MAOI) such as phenelzine, tranylcypromine, moclobemide, selegiline, linezolid and methylene blue. You must wait at least 7 days after you stop taking PRISTIQ before taking any MAOI.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRISTIQ. Talk about any health conditions or problems you may have, including if you:

- have or have a history of:
 - kidney problems
 - seizures (sudden and uncontrolled burst of electrical activity in the brain)
 - stroke
 - heart problems
 - aggression
 - abnormal levels of lipids (fats) in your blood
 - low sodium levels in your blood
 - bowel blockage or narrowing of the stomach or intestines
- have difficulty swallowing tablets whole.
- have a history or family history of mania or bipolar disorder.

- have a bleeding disorder or have been told that you have low blood platelets.
- have blood pressure problems.
- are taking any medicines, especially:
 - other medicines used to treat depression
 - medicines used to treat psychiatric disorders
 - opioids (including those used to treat pain or drug dependence)
 - medicines used to treat anxiety
 - medicines used to prevent blood clots (e.g., acetylsalicylic acid (ASA), blood thinners)
 - non-steroidal anti-inflammatory drugs (NSAIDs), used to relieve pain and reduce inflammation (e.g., ibuprofen, naproxen, diclofenac, celecoxib)
 - medicines used to treat migraines (e.g., triptans)
 - lithium, used to treat manic episodes of bipolar disorder
- are taking any nutritional or herbal supplements, including St. John's Wort.
- had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis.
- are pregnant or thinking about becoming pregnant, or if you are breast-feeding.

Other warnings you should know about:

Do NOT stop taking PRISTIQ without talking to your healthcare professional first, as it may cause unwanted side effects. These include irritability, agitation, aggression, dizziness, intense feelings of depression, numbness, tingling, burning or prickling sensations, anxiety, confusion, headache, low or high energy level, ringing in the ears, seizures (sudden and uncontrolled burst of electrical activity in the brain), vision changes and high blood pressure.

Activation of mania: Some patients with bipolar disorder (also known as manic depression) may enter into a manic phase when they start taking PRISTIQ. Tell your healthcare professional if you experience symptoms of mania such as excessive physical activity, overactive behaviour or thoughts, increased energy, trouble sleeping, racing thoughts, reckless behaviour, excessive happiness or irritability, talking more or faster than usual.

Angle-closure glaucoma: PRISTIQ can cause an acute attack of glaucoma. Having your eyes examined before you take PRISTIQ could help identify if you are at risk of having angle-closure glaucoma. Seek immediate medical attention if you experience:

- eye pain;
- changes in vision;
- swelling or redness in or around the eye.

Serotonin toxicity (also known as serotonin syndrome): PRISTIQ can cause serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin toxicity if you take PRISTIQ with certain antidepressants or migraine medications. Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Falls and fractures: Taking PRISTIQ may increase your risk of breaking a bone if you are elderly, have osteoporosis or have other major risk factors for breaking a bone. You should take extra care to avoid falls, especially if you get dizzy or have low blood pressure.

Effects on sexual function: Taking medicines like PRISTIQ may cause symptoms of sexual dysfunction. In some cases these symptoms have continued after stopping PRISTIQ treatment. Talk to your healthcare professional if you experience symptoms such as a decrease in sexual desire, performance or satisfaction.

Pregnancy: Only take PRISTIQ during pregnancy if you and your healthcare professional have discussed the risks and have decided that you should. If you take PRISTIQ near the end of your pregnancy, you may be at a higher risk of heavy vaginal bleeding shortly after birth. If you become pregnant while taking PRISTIQ, tell your healthcare professional **right away**.

Effects on newborns: In some cases, babies born to a mother taking PRISTIQ during pregnancy may require hospitalization, breathing support and tube feeding. Be ready to seek medical help for your newborn if they:

- have trouble breathing or feeding;
- have muscle stiffness, or floppy muscles (like a rag doll);
- have seizures (sudden and uncontrolled burst of electrical activity in the brain);
- are shaking (jitteriness);
- are constantly crying

Breast-feeding: PRISTIQ can pass into breast milk and may harm a breastfed baby. Only take PRISTIQ while you are breast-feeding if you and your healthcare professional have discussed the risks and have decided that you should.

Driving and using machines: Until you know how PRISTIQ affects you, do not drive or operate a vehicle or potentially dangerous machinery.

Monitoring and tests: Your healthcare professional may do tests, including blood tests, before you take PRISTIQ and regularly during your treatment. These tests will monitor:

- your blood pressure;
- your levels of cholesterol and triglycerides (types of fat) in your blood.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

Do not take PRISTIQ if you:

- are taking, or have taken in the last 14 days, any MAOIs such as phenelzine, tranylcypromine, moclobemide, selegiline, linezolid and methylene blue. You must wait at least 7 days after you stop taking PRISTIQ before taking any MAOI.

Before taking PRISTIQ, tell your healthcare professional if you take the following medicines:

- other medicines that contain desvenlafaxine, or venlafaxine
- other antidepressants, such as other SNRIs, selective serotonin reuptake inhibitors (SSRIs) and certain tricyclic antidepressants
- medicines used to treat psychiatric disorders (antipsychotics)
- amphetamines, used to treat conditions such as narcolepsy (uncontrollable urge to sleep), and attention deficit hyperactivity disorder (ADHD)
- lithium, used to treat manic episodes of bipolar disorder
- opioid medicines, used to treat pain or drug dependence, such as methadone, tramadol, buprenorphine, fentanyl, tapentadol, meperidine, pentazocine
- dextromethorphan, used to relieve coughs
- triptans, used to treat migraines
- tryptophan supplements
- St. John's Wort, a herbal remedy

Taking PRISTIQ with any of these medicines may cause serious drug interactions (e.g., serotonin toxicity). Ask your healthcare professional if you are unsure.

The following may also interact with PRISTIQ:

- medicines used to treat anxiety
- medicines to treat fungal infections such as ketoconazole
- benzodiazepines (used to treat anxiety, seizures and insomnia) such as midazolam
- medicines that affect your electrolyte levels such as diuretics ("water pills")
- medicines that can affect how your blood clots such as warfarin, acetylsalicylic acid (ASA), and non-steroidal anti-inflammatory drugs (NSAIDs)
- nutritional or herbal supplements
- alcohol. It is recommended to avoid drinking alcohol while taking PRISTIQ.

How to take PRISTIQ:

- It is very important that you take PRISTIQ exactly as your healthcare professional has instructed.
- Do not change your dose without talking to your healthcare professional.

- Your healthcare professional will tell you when to stop taking PRISTIQ. Always follow your healthcare professional's instructions on how to lower your dose carefully and safely to avoid experiencing withdrawal symptoms.
- Continue to take PRISTIQ even if you do not feel better as it may take several weeks for your medicine to start working.
- Take PRISTIQ:
 - once a day,
 - at the same time each day,
 - with or without food.
- Swallow tablets whole with a glass of water. Do not chew, divide or crush tablets.
- The medication in PRISTIQ is packed within a non-absorbable shell. This shell has been specially designed to slowly release the medicine at a constant rate over time so that the body can absorb it. The shell does not dissolve completely after all the medicine has been released, and you may sometimes notice it in your stool. Do not be concerned, this is normal.

Usual dose:

The usual dose is 50 mg once daily. Your healthcare professional may increase your dose if you need it.

Overdose:

If you think you, or a person you are caring for, have taken too much PRISTIQ, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

What are possible side effects from using PRISTIQ?

These are not all the possible side effects you may have when taking PRISTIQ. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of PRISTIQ may include:

- nausea, vomiting, diarrhea, constipation, abdominal discomfort or pain, feeling bloated (gas), dry mouth
- headache, dizziness, vertigo (feeling like you are spinning)
- chills
- lack of energy
- flu (fever, body aches, cough), stuffy nose, nosebleeds
- poor appetite, change in tastes, changes in weight
- burning or prickling sensation in the hands, arms, legs, or feet
- coldness in hands and feet
- difficulty to fall or stay asleep, sleepiness
- excessive sweating, skin rash, sensitivity to light
- abnormal dreams
- yawning
- hot flashes
- hair loss

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Hypertension (high blood pressure): headache, stronger and possibly faster heartbeat, chest pain, dizziness, excessive tiredness, and blurred vision. Sometimes, the increase in blood pressure could be severe enough to require urgent medical attention		✓	
Sexual problems: abnormal ejaculation or impotence in men, decreases in sexual desire, performance and satisfaction		✓	
Symptoms after discontinuation or dose reduction: loss of appetite or weight, anxiety, restlessness, aggression, confusion, convulsions, coordination	✓		

problems, diarrhea, dizziness, dry mouth, fatigue, headache, rapid mood swings, nausea, nightmares, tingling of the skin, sleep disturbances, sweating, ringing in the ears or vomiting			
Tachycardia (abnormally fast heartbeat): dizziness, light headedness, shortness of breath, racing heart		✓	
UNCOMMON			
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue, (hypotension may occur when you go from lying or sitting to standing up)		✓	
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat			✓
Myocardial ischemia (lack of blood flow to the heart which can lead to heart attack): sudden chest pain, pressure or discomfort, feeling faint, feeling anxious, shortness of breath, irregular heartbeat, nausea, sudden heavy sweating			✓
Severe skin reactions: raised red or purple skin patches, possibly with blister or crust in the center, possibly swollen lips, mild itching or burning; skin redness, blistering and/or			✓

peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, can be accompanied with fever, chills, headache, cough, body aches or swollen glands			
Urinary retention (inability to urinate or empty or loss of control of the bladder): pain		✓	
RARE			
Angle-closure glaucoma: blurred vision, halos around lights, eye pain and redness, nausea and vomiting, severe headache			✓
Hallucinations (seeing or hearing things that are not there)		✓	
Hyponatremia (low sodium in the blood): lack of energy, confusion, muscular twitching, achy, stiff or uncoordinated muscles, seizure, coma		✓	
New or worsened emotional or behavioural problems: agitation, feeling detached from one's self, anger, aggression, anxiety, violent thoughts		✓	
Mania: elevated or irritable mood, decreased need for sleep, racing thoughts		✓	
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen		✓	
Seizures (sudden and uncontrolled burst of electrical activity in the brain): confusion, staring, changes in behaviour and emotions, can occur with or without loss of consciousness,			✓

muscle twitching or other movements			
Serotonin toxicity (also known as serotonin syndrome): mental changes such as agitation, hallucinations, confusion, or other changes in mental status; coordination problems, uncontrolled muscle spasms, or muscle twitching (overactive reflexes); restlessness, shaking, shivering, racing or fast heartbeat, high or low blood pressure, sweating or fever, nausea, vomiting, or diarrhea, muscle rigidity (stiff muscles), tremor, loss of muscle control			✓
Uncontrollable movements of the body or face		✓	
UNKNOWN FREQUENCY			
Low Platelets: Bruising or unusual bleeding from the skin or other areas			✓
Akathisia (a type of movement disorder): a feeling of inner restlessness accompanied by mental distress and an inability to sit or stand still.		✓	
Allergic reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			✓
Gastrointestinal bleeding (bleeding in the stomach or bowels): black, tarry stool, blood in the stool, vomiting blood			✓
Self-harm or Suicide: thoughts or actions about hurting or killing yourself			✓

<p>Syndrome of inappropriate antidiuretic hormone secretion (SIADH): concentrated urine (dark in colour), feel or are sick, muscle cramps, confusion and fits (seizures) which may be due to inappropriate secretion of ADH (antidiuretic hormone)</p>			✓
<p>Urinary tract infection (infection of the urinary system, including kidneys, ureters, bladder and urethra): pain or burning sensation while urinating, frequent urination, blood in urine, pain in the lower abdomen, strong smelling urine, cloudy urine</p>		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at 15°C to 30°C.
- Keep out of reach and sight of children.
- Do not use PRISTIQ after the expiration date (EXP), which is stated on the package. The expiration date refers to the last day of that month.
- Medicines should not be disposed of in wastewater or in household waste. Ask your

pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If you want more information about PRISTIQ:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001 (Medical Information).

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