

PRISTIQ[®] EXTENDED-RELEASE TABLETS

Desvenlafaxine succinate (50 mg, 100 mg)

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What PRISTIQ is used for

PRISTIQ is used in the treatment of major depressive disorder (MDD).

How PRISTIQ works

PRISTIQ belongs to a class of medications called serotonin-noradrenaline reuptake inhibitors (SNRIs). Serotonin and noradrenaline are chemical messengers that allow certain nerves in the brain to work. PRISTIQ tablets potentiate the effects of these two messengers. Experts think this is how it helps to restore your feeling of wellness.

Before you use PRISTIQ

- When you must not use it

Do not take PRISTIQ

- if you are allergic to desvenlafaxine, venlafaxine or any of the other ingredients of this medicine;
- if you are also taking, or have taken within the last 14 days, any medicines known as Monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking a reversible MAOI together with PRISTIQ or in whom intravenous methylene blue has been administered can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking PRISTIQ before you take any MAOI.

Pregnancy and lactation

You should use PRISTIQ only after discussing the potential benefits and the potential risks to your unborn child with your doctor.

PRISTIQ crosses the human placenta. If you are taking this medicine during pregnancy, your baby may not feed properly, have trouble breathing, or may encounter prolonged hospitalization. If your baby has these symptoms when it is born and you are concerned, contact your doctor who will be able to advise you.

Consuming PRISTIQ during pregnancy may cause high blood pressure, sometimes associated with fluid accumulation, excessive post-delivery bleeding.

Discontinuing the medicine may lead to a recurrence of depression. Please inform your doctor if your symptoms persist or increase after discontinuing the medicine.

PRISTIQ passes into breast milk and its effect in infants have not been established. Therefore, you should discuss the matter with your doctor, and he/she will prescribe this medicine only if the expected benefits outweigh the possible risks.

- Before you start to use it

If any of the following apply to you, please tell your doctor before taking PRISTIQ:

- if you take PRISTIQ near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor should be aware that you are taking PRISTIQ so they can advise you.
- if you have a history of, or if someone in your family has had, mania or hypomania;

- if you are depressed and have thoughts of harming or killing yourself. You may be more likely to think like this if you have previously had thoughts about killing yourself or harming yourself or if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behavior in children, adolescents and young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant;
- if you are using other medicines that taken together with PRISTIQ could increase the risk of developing serotonin syndrome. Signs and symptoms of serotonin syndrome may include restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhea, coma, nausea and vomiting. In its most severe form, serotonin syndrome can resemble neuroleptic malignant syndrome (NMS). Signs and symptoms of NMS may include high temperature with rigid muscles, confusion or agitation, and sweating;
- if you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye);
- if you have a history of high blood pressure;
- if you have a history of heart problems, such as a previous heart attack;
- if you have a history of stroke;
- if you have a history of fits (seizures);
- if you have a history of low sodium levels in your blood (hyponatraemia);
- if you are taking water tablets;
- if you have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders), or if you are taking other medicines that may increase the risk of bleeding;
- if you have raised cholesterol or lipid levels.

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- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Your doctor should decide whether you can take PRISTIQ with other medicines.

In particular tell your doctor if you are taking:

- other medicines to treat depression, for instance MAOIs, other SNRIs, selective serotonin reuptake inhibitors (SSRIs), tricyclics (e.g., desipramine) or medicines containing lithium;
- venlafaxine hydrochloride or other products containing desvenlafaxine succinate;
- fentanyl and its analogues (used to manage pain);
- dextromethorphan (used as a cough suppressant);
- tapentadol (helps to relieve pain);
- meperidine (treat moderate-to-severe pain);
- methadone (used to treat pain and also for detoxification or maintenance treatment of an opioid drug addiction);
- pentazocine (used to relieve moderate to severe pain);
- methylene blue (used to treat methemoglobinemia);
- triptans (used for migraine);
- amphetamines (used in the treatment of attention deficit hyperactivity disorder (ADHD), sleep disorders and obesity);
- medicines containing sibutramine (used for weight loss);
- medicines containing tramadol (used to treat severe pain);
- products containing St. John's Wort (also called *Hypericum perforatum*, a natural or herbal remedy used to treat mild depression);
- medicines containing linezolid, an antibiotic (used to treat infections);
- products containing tryptophan (used for problems such as sleep and depression);
- antipsychotics (used to treat a disease called schizophrenia);

- medicines containing ketoconazole (an antifungal medicine);
- medicines containing midazolam (for inducing sleep and treating anxiety).

How to use PRISTIQ

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The usual dose is 50 mg taken once daily with or without food. The maximum dose is 200 mg/day.

If you have kidney problems, talk to your doctor, since your dose of this medicine may need to be different.

The safety and effectiveness of PRISTIQ in individuals under 18 years of age have not been established.

- When to use it

Use as directed by your doctor or pharmacist.

PRISTIQ should be taken at approximately the same time each day with or without food. Tablets must be swallowed whole with fluid and not divided, crushed, chewed or dissolved.

- How long to use it

Continue taking PRISTIQ for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Overdose cases (including death) have been reported when PRISTIQ is taken together with alcohol and/or other medicinal products.

While you are using it

- Things you must do

- Visit your doctor if you cannot tolerate the side effects following a dose reduction or upon discontinuation of the medication.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking PRISTIQ.
- Tell your doctor immediately if you become pregnant while taking this medication.
- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.
- You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.
- You should avoid alcohol while you are taking PRISTIQ.
- Inform your doctor, if you notice symptoms of sexual dysfunction, even after you stop taking PRISTIQ.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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Do not give PRISTIQ to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Do not drive or use any tools or machines until you know how this medicine affects you.

PRISTIQ is prepared as a matrix tablet that slowly releases the medicine inside your body. You may notice something in your stool that looks like a tablet, but it is an empty matrix. Seeing the empty matrix is not a cause for concern. There is no need to take an extra tablet. The active medication has already been absorbed by the time you see the matrix.

Side effects

Like all medicines, PRISTIQ can cause side effects, although not everybody gets them.

If any of the following happen, do not take more PRISTIQ. Tell your doctor immediately, or go to the casualty department at your nearest hospital:

Frequent side effects

- nausea, dry mouth, constipation, diarrhoea, vomiting;
- fatigue, chills, weakness (asthenia), feeling nervous or anxious;
- headache, dizziness, sleepiness, tremor, pins and needles sensation, altered taste sensation, disturbance in attention;
- difficulty sleeping, anxiety, abnormal dreams, nervousness, irritability;
- sweating (including night sweats), rash;
- muscle stiffness, palpitations (feeling your heartbeat), fast heartbeat;

- ringing in the ears (tinnitus), vertigo;
- blurred vision, dilated pupils;
- weight gain or loss, increased blood pressure, decreased appetite, abnormal liver function test;
- sexual dysfunction such as reduced sex drive, lack of orgasm, erectile dysfunction (impotence), abnormal ejaculation/orgasm (males); symptoms may persist despite discontinuation of medication;
- yawning, sudden feeling of heat;

Side effects are known to occur when people stop using this medicine, especially when it is stopped suddenly or the dose is reduced too quickly:

- lack of sleep (insomnia), irritability, anxiety, agitation, dysphoric mood (characterized by sadness, numbness, mood swings), extreme changes in mood (emotional lability), elevated mood and hyperactivity (hypomania)
- a sensation of losing balance (dizziness), confusion, headache, fits, sensory disturbances such as electric shock
- blurred vision
- lethargy
- hypertension
- ringing or buzzing in the ears (tinnitus)
- suicidal thoughts/suicide, aggression

Mostly these symptoms are self-limiting, however if the symptoms persist or become severe, visit your doctor. Your doctor may consider resuming the medicine in such cases.

Side effects from discontinuing antidepressant medication may occur if you are switched from other antidepressants to PRISTIQ. Your doctor may gradually reduce the dose of your initial antidepressant medication to help reduce these side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →

Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of PRISTIQ

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Keep the blister in the outer carton.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

50 mg extended-release tablets
Light pink, square (pyramid, one sided), film coated tablets debossed "W" over '50' on the flat side.

100 mg extended-release tablets
Reddish orange, square (pyramid, one sided), film coated tablets debossed "W" over '100' on the flat side.

- Ingredients

- Active ingredient

Desvenlafaxine succinate

- Inactive ingredients

Opadry II Pink, Magnesium Stearate NF/Ph. Eur, Talc, microcrystalline cellulose (Avicel PH 102) Ph Eur/NF, Hypromellose 2208, Microcrystalline Cellulose, Purified water.

- MAL number:

PRISTIQ Tablets 50 mg
MAL20091918ARZ
PRISTIQ Tablets 100 mg
MAL20091919AZ

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Desvenlafaxine succinate (50 mg, 100 mg)

Manufacturer

Pfizer Ireland Pharmaceuticals Unlimited
Company,
Little Connell, Newbridge, Co. Kildare,
Ireland

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11
Wisma Averis, Tower 2
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No. 8 Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

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