

Venlafaxine Morningside

150 mg prolonged-release hard capsules

venlafaxine hydrochloride

Venlafaxine Morningside 150 mg prolonged-release hard capsules may be referred to in the leaflet as Venlafaxine PR or Venlafaxine PR capsules.

IMPORTANT THINGS YOU SHOULD KNOW ABOUT VENLAFAXINE PR

Please read all of this leaflet before you start to take your medicine as it contains important information about Venlafaxine PR.

- Venlafaxine PR is used to treat depression, severe and persistent anxiety known as generalised anxiety disorder (GAD), social anxiety disorder (also known as social phobia) and panic disorder (panic attacks).
- Venlafaxine PR is not for use in children and adolescents – see in section 2 'Children and adolescents'.

If you have any concerns about how you feel, or about this medication, it is important that you talk to your doctor – even if you feel anxious or worried about doing so.

You may find it helpful to tell a friend or relative that you are depressed or suffering from an anxiety disorder, and that you have been prescribed this medication; it might be useful to show them this leaflet.

Venlafaxine PR may not start to work immediately.

- Some people taking antidepressants may feel worse before feeling better. Your doctor may ask to see you again a couple of weeks after you start treatment and then regularly until you start to feel well again. Tell your doctor if you do not start to feel better.
- **Some people who are depressed may think of harming or killing themselves. If this happens you should see your doctor or go to a hospital straight away** – see in section 2 'Thoughts of suicide and worsening of your depression or anxiety disorder'.
- **If you take too many capsules it is important to seek immediate medical attention, even if you feel well, because of the risk of serious side effects.**
- **Do not stop taking Venlafaxine PR or change your dose without the advice of your doctor even if you feel better.** If you stop taking Venlafaxine PR abruptly you may get withdrawal reactions – see in section 3 'If you stop taking Venlafaxine PR'.
- **If you have heart problems such as fast or irregular heart rate or high blood pressure you should talk to your doctor before taking Venlafaxine PR** – see in section 2 'Before you take Venlafaxine PR'.
- **Taking certain other medicines with Venlafaxine PR may cause problems. You should tell your doctor if you are taking any other medicines** – see in section 2 'What you need to know before you take Venlafaxine PR'.
- **See your doctor without delay** if you feel restless and feel like you can't keep still, feel 'high' or very over-excited, have jerky muscle movements which you can't control. See section 4 – 'Possible side effects' for other important information.

If you are pregnant, or intend to become pregnant, or breast-feeding, you should talk to your doctor – see in section 2 'Pregnancy and breast-feeding'.

More information on all of these points is provided in the rest of this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Venlafaxine PR is and what it is used for

2. What you need to know before you take Venlafaxine PR

3. How to take Venlafaxine PR

4. Possible side effects

5. How to store Venlafaxine PR

6. Contents of the pack and other information

1. What Venlafaxine PR is and what it is used for

Venlafaxine PR contains the active substance venlafaxine. Venlafaxine PR is an antidepressant that belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). This group of medicines is used to treat depression and other conditions such as anxiety disorders. It is thought that people who are depressed and/or anxious have lower levels of serotonin and noradrenaline in the brain. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

Venlafaxine PR is a treatment for adults with depression. It is also a treatment for adults with the following anxiety disorders: generalised anxiety disorder, social anxiety disorder (fear or avoidance of social situations) and panic disorder (panic attacks). Treating depression or anxiety disorders properly is important to help you get better. If it is not treated, your condition may not go away and may become more serious and more difficult to treat.

2. What you need to know before you take Venlafaxine PR

Do not use Venlafaxine PR if:

- If you are allergic to venlafaxine or any of the other ingredients of this medicine (listed in section 6). If you are also taking, or have taken within the last 14 days, any medicines known as irreversible monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking an irreversible MAOI together with Venlafaxine PR, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Venlafaxine PR before you take any MAOI (see also the section entitled "Other medicines and Venlafaxine PR" and the information in that section about 'Serotonin Syndrome').

Warning and precautions:

Do not drink alcohol while being treated with Venlafaxine PR as it can lead to extreme tiredness and unconsciousness. Concomitant use with alcohol and/or certain medicines can make your symptoms of depression and other conditions, such as anxiety disorders worse.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when you first start taking antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer.

You may be more likely to think like this if you:

- have previously had thoughts about killing yourself or harming yourself
- are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychotropic

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 tell an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Talk to your doctor before taking Venlafaxine PR if you:

- use other medicines that taken together with Venlafaxine PR could increase the risk of developing serotonin syndrome, a potentially life-threatening condition (see the section "Other medicines and Venlafaxine PR").

- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

- have a history of heart problems: abnormal heart rhythm.

- have a history of fits (seizures).

- have a history of low sodium levels in your blood (hyponatraemia).

- 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 e.g. warfarin (used to prevent blood clots).

- if you are pregnant (see 'Pregnancy and breast-feeding').

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If you take Venlafaxine PR 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 or midwife should be aware that you are taking Venlafaxine PR so they can advise you.

Venlafaxine PR passes into breast milk. There is a risk of an effect on the baby. Your baby may experience irritability, shaking, floppiness, persistent crying and difficulty in sleeping. Therefore, you should discuss the matter with your doctor, and he/she will decide whether you should stop breast-feeding or stop the therapy with this medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Venlafaxine PR may make you feel drowsy. Be careful driving or operating dangerous machinery until you know how it affects you.

Important information about some of the ingredients of Venlafaxine PR

The colour Allura red (E129) and Sunset yellow FCF (E110) may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Venlafaxine PR

Always take Venlafaxine PR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended starting dose for the treatment of depression, generalised anxiety disorder and social anxiety disorder is 75 mg per day. The dose can be raised by your doctor gradually, and if needed, even up to a maximum dose of 375 mg daily for depression. If you are being treated for panic disorder, your doctor will start with a lower dose (37.5 mg) and then increase the dose gradually. The maximum dose for generalised anxiety disorder, social anxiety disorder and panic disorder is 225 mg/day.

Take Venlafaxine PR at approximately the same time each day, either in the morning or in the evening. Capsules must be swallowed whole with fluid and not opened, crushed, chewed or dissolved.

Venlafaxine PR should be taken with food. If you have liver or kidney problems, talk to your doctor, since your dose of this medicine may need to be different.

Do not stop taking this medicine without talking to your doctor (see the section "If you stop taking Venlafaxine PR").

Children and adolescents

The use of Venlafaxine PR in children and adolescents (under the age of 18) is not recommended (see also section 2).

Impairment of the liver or kidneys

If you suffer from liver or kidney problems, the dosage may be reduced by your doctor.

If you take more Venlafaxine PR than you should

Call your doctor or pharmacist immediately if you take more of this medicine than the amount prescribed by your doctor.

Overdose can be life-threatening, especially with concomitant use of alcohol and/or certain medicines (see "Other medicines and Venlafaxine PR").

Symptoms of overdose: A rapid heartbeat, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

If you forget to take Venlafaxine PR

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take a double dose to make up for a forgotten dose. Do not take more than the daily amount of Venlafaxine PR that has been prescribed for you in one day.

If you stop taking Venlafaxine PR

Do not stop taking your treatment or reduce the dose without the advice of your doctor even if you feel better.

If your doctor thinks that you no longer need Venlafaxine PR, he/she may ask you to reduce your dose slowly before stopping treatment altogether. 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. Some patients may experience symptoms such as tiredness, dizziness, light-headedness, headache, sleeplessness, nightmares, dry mouth, loss of appetite, nausea, diarrhoea, nervousness, agitation, confusion, ringing in the ears, tingling or rarely electric shock sensations, weakness, sweating, seizures, or flu-like symptoms. Your doctor will advise you on how you should gradually discontinue Venlafaxine PR treatment.

If you experience any of these or other symptoms that are troublesome, ask your doctor for further advice. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

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

Uncommon (may affect up to 1 in 100 people)

- Swelling of the face, mouth, tongue, throat, hands, or feet, and/or a raised itchy rash (hives), trouble swallowing or breathing.

Rare (may affect up to 1 in 1,000 people)

- Chest tightness, wheezing, trouble swallowing or breathing
- Severe skin rash, itching or hives (elevated patches of red or pale skin that often itch)

• Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting. In its most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test)

• Signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms. This may be the result of a blood disorder which leads to an increased risk of infection

• Severe rash, which may lead to severe blistering and peeling of the skin

• Unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.

Frequency not known (cannot be estimated from the available data)

- Signs and symptoms of a condition called 'stress cardiomyopathy' which may include chest pain, shortness of breath, dizziness, fainting, irregular heartbeat.

Other side effects that you should tell your doctor about include (The frequency of these side effects are included in the list 'Other side effects that may occur' below):

- Coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- Black (tarry) stools or blood in stools
- Itching, yellow skin or eyes, or dark urine, which may be symptoms of inflammation of the liver (hepatitis)
- Heart problems, such as fast or irregular heart rate, increased blood pressure
- Eye problems, such as blurred vision, dilated pupils
- Nerve problems, such as dizziness, pins and needles, movement disorder (muscle spasms or stiffness), seizures or fits
- Psychiatric problems, such as hyperactivity and feeling unusually overexcited (see the section 'How to take PR')
- Venlafaxine PR, if you stop taking Venlafaxine PR
- Prolonged bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy and breast-feeding' in section 2 for more information.

Do not be concerned if you see small white balls or granules in your stools after taking this medicine. Inside Venlafaxine PR capsules are the active ingredients (small white balls) that contain the active ingredient (venlafaxine). These spheroids are released from the capsule into your stomach. As they travel through your stomach and intestines, venlafaxine is slowly released. The spheroid 'shell' does not dissolve and is passed out in your stools. So, even though you may see spheroids in your stools, your dose of medicine has been absorbed.

Other side effects that may occur

Very common (may affect more than 1 in 10 people)

- Headache, drowsiness, dizziness
- Insomnia
- dry mouth, constipation, nausea

- Sweating (including night sweats)

Common (may affect up to 1 in 10 people)

- Appetite decreased
- Confusion; feeling separated (or detached) from yourself; lack of orgasm; decreased libido; agitation; nervousness; abnormal dreams
- Tremor; a sensation of restlessness or an inability to sit or stand still; pins and needles; altered taste sensation; increased muscle tonus
- Visual disturbance including blurred vision; dilated pupils; inability of the eye to automatically change focus from distant to near objects
- Ringing in the ears (tinnitus)
- Fast heartbeat; palpitations
- Increase in blood pressure; flushing
- Shortness of breath; yawning
- Vomiting; diarrhoea
- Mild rash; itching
- Increased frequency in urination; inability to pass urine; difficulties passing urine
- Menstrual irregularities such as increased bleeding or increased irregular bleeding; abnormal ejaculation/ orgasm (males); erectile dysfunction (impotence)
- Weakness (asthenia); fatigue; chills
- Weight gain; weight loss
- Increased cholesterol
- Sedation.

Uncommon (may affect up to 1 in 100 people)

- Over activity, racing thoughts and decreased need for sleep (mania)

• Hallucinations; feeling separated (or detached) from reality; abnormal orgasm (females); lack of feeling or emotion; feeling over-excited; grinding of the teeth

• Fainting; involuntary movements of the muscles; impaired coordination and balance

• Feeling dizzy (particularly when standing up too quickly); decrease in blood pressure

• Vomiting blood, black tarry stools (faeces) or blood in stools; which can be a sign of internal bleeding

• Sensitivity to sunlight; bruising; abnormal hair loss

• Inability to control urination

• Stiffness, spasms and involuntary movements of the muscles

• Slight changes in blood levels of liver enzymes

• Agitation.

Rare (may affect up to 1 in 1,000 people)

- Seizures or fits

• Coughing, wheezing and shortness of breath which may be accompanied by a high temperature which are symptoms of inflammation of the lungs associated with an increase in white blood cells (pulmonary eosinophilia)

• Disorientation and confusion often accompanied by hallucination (delirium)

• Excessive water intake (known as SIADH)

• Decrease in blood sodium levels

• Severe eye pain and decreased or blurred vision

• Abnormal, rapid or irregular heartbeat, which could lead to fainting

• Severe abdominal or back pains (which could indicate a serious problem in the gut, liver or pancreas)

• Itching, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis).

Very rare (may affect up to 1 in 10,000 people)

- Prolonged bleeding, which may be a sign of reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding

• Abnormal breast milk production

• Unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins).

Frequency not known (cannot be estimated from the available data)

- Suicidal ideation and suicidal behaviours; cases of suicidal ideation and suicidal behaviours have been reported during venlafaxine therapy or early after treatment discontinuation (see section 2, What you need to know before you take Venlafaxine PR)

• Aggression

• Vertigo.

Venlafaxine PR sometimes causes unwanted effects that you may not be aware of, such as increases in blood pressure or abnormal heart beat, slight changes in blood levels or liver enzymes, sodium or cholesterol. More rarely, Venlafaxine PR may reduce the function of platelets in your blood, leading to an increased risk of bruising or bleeding. Therefore, your doctor may wish to do blood tests occasionally, particularly if you have been taking Venlafaxine PR for a long time.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

UK:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland:

HPRA Pharmacovigilance,

Website: www.hpra.ie;

5. How to store Venlafaxine PR

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and blisters after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Store in the original container to protect from moisture.

Do not use this medicine if you notice that the capsules are sticky or other visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Venlafaxine PR capsules contain

The active substance is venlafaxine hydrochloride equivalent to 150 mg venlafaxine.

The other ingredients are: microcrystalline cellulose, copovidone, ethyl cellulose, magnesium stearate, povidone, colloidal silicon dioxide, talc.

The capsule shell contains gelatine, titanium dioxide (E171), brilliant blue FCF (E133), allura red (E129), sunset yellow FCF (E110). The printing ink contains:

shellac, propylene glycol, sodium hydroxide, povidone, titanium dioxide (E171).

The active substance and ingredients are used to make white to off-white round biconvex film coated mini tablets of 12.5 mg. The 150 mg capsule contains 12 mini tablets.

What Venlafaxine PR capsules look like and contents of the pack

The 150 mg capsules are opaque, dark orange hard gelatin capsules having white coloured thick and thin radial circular bands on both ends of the capsules.

Venlafaxine PR capsules are available in blister packs of 10, 14, 15, 20, 28, 30, 56, 60 or 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicine is authorised in the Member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Ireland – Venlafaxine XL 150 mg prolonged-release hard capsules

UK – Venlafaxine XL 150 mg prolonged-release hard capsules

& Venlafaxine Morningside 150 mg prolonged-release hard capsules

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