

VENLAFAXINE 37.5 mg TABLETS

VENLAFAXINE 75 mg TABLETS

IMPORTANT THINGS YOU SHOULD KNOW ABOUT Venlafaxine

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

Venlafaxine is used to treat depression.

Venlafaxine 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 may not start to work immediately. Some people taking antidepressants may feel worse before feeling better. Your doctor may ask to see you again in 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 tablets 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 or change your dose without the advice of your doctor even if you feel better. If you stop taking Venlafaxine abruptly you may get withdrawal reactions – see in section 3 'If you stop taking Venlafaxine'.

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 – see in section 2 'Before you take Venlafaxine'.

Taking certain other medicines with Venlafaxine 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'.

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 is and what it is used for
2. What you need to know before you take Venlafaxine
3. How to take Venlafaxine
4. Possible side effects
5. How to store Venlafaxine
6. Contents of the pack and other information

1. WHAT VENLAFAXINE IS AND WHAT IT IS USED FOR

The name of your medicine is Venlafaxine 37.5 mg Tablets or Venlafaxine 75 mg Tablets (referred to as Venlafaxine throughout this leaflet).

Venlafaxine contains the active substance venlafaxine.

Venlafaxine 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. It is thought that people who are depressed and/or anxious have lower levels of serotonin and norepinephrine in the brain. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and norepinephrine in the brain.

Venlafaxine is a treatment for adults with depression. Treating depression 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

Do not take Venlafaxine

- If you are allergic to venlafaxine or any of the other ingredients of Venlafaxine (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, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Venlafaxine before you take any MAOI (see also the section entitled "Other medicines and Venlafaxine" and the information in that section about "Serotonin syndrome").

Warnings and precautions

Talk to your doctor or pharmacist **before** taking Venlafaxine:

- If you use other medicines that taken together with Venlafaxine, could increase the risk of developing serotonin syndrome, a potentially life-threatening condition (see the section "Other medicines and Venlafaxine").
- 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.
- If you have been told you have an abnormal heart rhythm.
- If you have a history of fits (seizures).
- If you have a history of low sodium levels in your blood (hyponatraemia).
- 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 e.g., warfarin (used to prevent blood clots).
- If you have a history of, or if someone in your family has had, mania or bipolar disorder (feeling over-excited or euphoric).
- If you have a history of aggressive behaviour.
- If you have a history of bleeding disorders, or if you are pregnant (see 'Pregnancy').

Venlafaxine may cause a sensation of restlessness or an inability to sit or stand still during the first few weeks of treatment. You should tell your doctor if this happens to you.

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 thoughts may be increased when you first start taking antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer. These thoughts

may also occur when your dose is decreased or during discontinuation of treatment with Venlafaxine. You may be more likely to think like this:

- If you have previously had thoughts about killing yourself or harming yourself.
- If you 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 psychiatric conditions who were treated with an antidepressant.

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 anxious, 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.

Dry mouth

Dry mouth is reported in 10% of patients treated with venlafaxine. This may increase the risk of tooth decay (caries). Therefore, you should take special care in your dental hygiene.

Diabetes

Your blood glucose levels may be altered due to Venlafaxine. Therefore, the dosage of your diabetes medicines may need to be adjusted.

Sexual problems

Medicines like Venlafaxine (so called SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Children and adolescents

Venlafaxine should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects, such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Venlafaxine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Venlafaxine for a patient under 18, and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Venlafaxine. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Venlafaxine in this age group has not yet been demonstrated.

Other medicines and Venlafaxine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor should decide whether you can take Venlafaxine with other medicines. Do not start or stop taking any medicines, including those bought without a prescription, natural and herbal remedies, before checking with your doctor or pharmacist.

- Monoamine oxidase inhibitors which are used to treat depression or Parkinson's disease **must not be taken with Venlafaxine**. Tell your doctor if you have taken these medicines within the last 14 days. (MAOIs: see the section "What you need to know before you take Venlafaxine").

Serotonin syndrome:

A potentially life-threatening condition or Neuroleptic Malignant Syndrome (NMS)-like reactions (see the section "Possible Side Effects") may occur with venlafaxine treatment, particularly when taken with other medicines. Examples of these medicines include:

- Triptans (used for migraine)
- Other medicines to treat depression, for instance SNRIs, SSRIs, tricyclics, or medicines containing lithium
- Medicines containing amphetamines (used to treat attention deficit hyperactivity disorder (ADHD), narcolepsy and obesity)
- Medicines containing linezolid, an antibiotic (used to treat infections)
- Medicines containing moclobemide, a MAOI (used to treat depression)
- Medicines containing sibutramine (used for weight loss)
- Medicines containing tramadol (a pain-killer), fentanyl, tapentadol, pethidine, pentazocine, buprenorphine (used to treat severe pain), buprenorphine/naloxone (used to treat opioid overdose)
- Medicines containing dextromethorphan (used to treat coughing)
- Medicines containing methadone (used to treat opioid drug addiction or severe pain)
- Medicines containing methylene blue (used to treat high levels of methaemoglobin in the blood)
- Products containing St. John's Wort (also called Hypericum perforatum, a natural or herbal remedy used to treat mild depression)
- Products containing tryptophan (used for problems such as sleep and depression)
- Antipsychotics (used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, unclear reasoning and becoming withdrawn)

Signs and symptoms of serotonin syndrome may include a combination of the following:

involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, increased muscle tension, restlessness, hallucinations, loss of coordination, fast heartbeat, body temperature above 38°C, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting. Contact your doctor when experiencing such symptoms.

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).

Tell your doctor immediately, or go to the casualty department at your nearest hospital if you think serotonin syndrome is happening to you.

You must tell your doctor if you are taking medicines that can affect your heart rhythm.

Examples of these medicines include:

- Antiarrhythmics such as quinidine, amiodarone, sotalol or dofetilide (used to treat abnormal heart rhythm)
- Antipsychotics such as thioridazine (See also Serotonin syndrome above)
- Antibiotics such as erythromycin or moxifloxacin (used to treat bacterial infections)
- Antihistamines (used to treat allergy)
- The following medicines may also interact with Venlafaxine and should be used with caution. It is especially important to mention to your doctor or pharmacist if you are taking medicines containing:
 - Ketoconazole (an antifungal medicine)
 - Haloperidol or risperidone (to treat psychiatric conditions)
 - Metoprolol (a beta blocker to treat high blood pressure and heart problems)
 - Oral contraceptives

Venlafaxine with food, drink and alcohol

Venlafaxine should be taken with food (see section 3 "How to take Venlafaxine").

You should avoid alcohol while you are taking Venlafaxine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask



your doctor or pharmacist for advice before taking this medicine. You should use Venlafaxine only after discussing the potential benefits and the potential risks to your unborn child with your doctor.

Make sure your midwife and/or doctor knows you are on Venlafaxine. When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you are taking Venlafaxine during pregnancy, in addition to having trouble breathing another symptom your baby might have when it is born is not feeding properly. If your baby has these symptoms when it is born and you are concerned, contact your doctor and/or midwife who will be able to advise you.

Venlafaxine passes into breast milk. There is a risk of an effect on the baby. 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 Venlafaxine.

If you take Venlafaxine 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 so they can advise you.

Driving and using machines

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

Important information about some of the ingredients of Venlafaxine

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. HOW TO TAKE VENLAFAXINE

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

The usual recommended starting dose is 75 mg per day in divided doses. The dose can be raised by your doctor gradually and, if needed, even up to a maximum dose of 375 mg daily for depression.

Take Venlafaxine at approximately the same time each day, in the morning and in the evening.

Venlafaxine should be taken with food.

If you have liver or kidney problems, talk to your doctor, since your dose of Venlafaxine may need to be different.

The 37.5mg tablets and 75mg tablets come in special "calendar" packs which help you remember to take your tablets when you should.

The following instructions will help you:

1. Remove a card.
2. Go to the correct day of the week.
3. Take the tablet from the card or part of the card, marked "AM", in the morning.
4. Your next tablet should be taken in the evening from the card or part of the card, marked "PM".
5. Continue taking a tablet every morning and evening.
6. When you have finished a card, move on to the next one.

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

If you take more Venlafaxine than you should

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

The symptoms of a possible overdose may include 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

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 that has been prescribed for you in one day.

If you stop taking Venlafaxine

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, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using Venlafaxine, especially when Venlafaxine is stopped suddenly or the dose is reduced too quickly. Some patients may experience symptoms such as suicidal thoughts, aggressiveness, 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, problems with eyesight and increase in blood pressure (which can cause headache, dizziness, ringing in the ears, sweating, etc).

Your doctor will advise you on how you should gradually discontinue Venlafaxine treatment. This can take a period of several weeks or months. In some patients, discontinuation may need to occur very gradually over periods of months or longer. 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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If any of the following happen, do not take more Venlafaxine. **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)

- 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)
- 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
- Itchiness, 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
- Withdrawal effects (see the section "How to take Venlafaxine, if you stop taking Venlafaxine")
- Prolonged bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop

Other side effects that may occur

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

- dizziness; headache; drowsiness
- insomnia
- nausea; dry mouth; constipation
- 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

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; 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

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
- 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)
- itchiness, 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)

- aggression
- vertigo (sensation of dizziness or spinning)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy' in section 2 for more information

Venlafaxine sometimes causes unwanted effects that you may not be aware of, such as increases in blood pressure or abnormal heartbeat; slight changes in blood levels of liver enzymes, sodium or cholesterol. More rarely, Venlafaxine 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 for a long time.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE VENLAFAXINE

Keep out of the sight and reach of children.

Do not use Venlafaxine after the expiry date, which is stated on the packaging.

This medicinal product does not require any special storage conditions.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Venlafaxine contains

The active substance is venlafaxine.

Each tablet contains either 37.5 mg or 75 mg venlafaxine as venlafaxine hydrochloride.

Other ingredients in these tablets are: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, magnesium stearate, ferric oxide yellow (E-172), ferric oxide red (E-172) and ferric oxide black (E-172).

What Venlafaxine looks like and contents of the pack

Venlafaxine 37.5 mg and Venlafaxine 75 mg are mottled-beige, round tablets.

Venlafaxine 37.5 mg and Venlafaxine 75 mg come in calendar packs of 28 and 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

DEXCEL® -PHARMA LTD., 7 Sopwith Way, Drayton Fields, Drayton, Northamptonshire, NN11 8PB, UK.

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