

Venlafaxine 37.5mg and 75mg tablets

Important things you need to know about venlafaxine

- Venlafaxine is for depression
 - Venlafaxine should not be given to anyone under 18 years of age (see section 3)
 - Venlafaxine may not work straight away. After you start treatment, you may feel worse before you feel better. It may take between two and four weeks before you start to feel better. Tell your doctor if you do not start to feel better
 - Some people who are depressed may think of harming or killing themselves. If you have these thoughts at any time, tell your doctor or go to a hospital straight away (see section 2 'Thoughts of suicide and worsening of your depression or anxiety disorder')
 - If you have taken too many tablets tell your doctor or go to a hospital straight away. Do this even if you feel well. This is because taking too much of this medicine can be dangerous
 - Do not stop taking your tablets or change the amount you take without checking with your doctor first. Keep taking them even if you feel better. If you stop taking venlafaxine suddenly you may get withdrawal reactions (see section 3)
 - Taking some other medicines with venlafaxine may cause problems. Tell your doctor if you are taking or have recently taken any other medicines (see section 2)
 - Tell your doctor straight away if you feel restless and can't keep still, feel 'high' or over-excited or have jerky muscle movements which you can't control (see section 4)
 - If you have problems with your heart or have high blood pressure, talk to your doctor before taking venlafaxine (see section 2)
 - If you are pregnant, planning to become pregnant, or are breast-feeding, talk to your doctor before taking venlafaxine (see section 2)
- There is more information on all of these points in the rest of this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1 What Venlafaxine tablets are and what they are used for

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 anxiety disorders in adults. 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 tablets are used to treat adults with depression. Treating depression properly is important. If it is not treated, your condition may not go away and may become more serious and more difficult to treat.

2 Before you take

Do not take Venlafaxine tablets if you

- are **allergic** to venlafaxine or any of the other ingredients of the tablets (see section 6). The tablets also contain sunset yellow (E110) which may cause allergic reactions.
- are taking or have recently taken (within the last 14 days) another medicine known as an **irreversible monoamine oxidase inhibitor or MAOI** (for depression or Parkinsons disease). Taking an irreversible MAOI together with other medicines, including Venlafaxine tablets, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Venlafaxine tablets before you take any irreversible MAOI (see also the section 'Taking other medicines').

Take special care with Venlafaxine tablets if you

- use **other medicines** that taken concomitantly with Venlafaxine tablets could increase the risk of developing serotonin syndrome or neuroleptic malignant syndrome.
- have **eye problems**, such as certain kinds of glaucoma (increased pressure in the eye).
- have a history of **high blood pressure**.
- have a history of **heart problems**.
- 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.
- have **high cholesterol** levels or they get higher.
- have a history of, or if someone in your family has had, **mania or bipolar disorder** (feeling over-excited or euphoric).
- have a history of **aggressive behaviour**.
- have **diabetes**.

Venlafaxine tablets may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.

If any of these conditions apply to you, please talk with your doctor before taking Venlafaxine tablets.

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.
- 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 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.

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 with your dental hygiene whilst taking these tablets.

Use in children and adolescents under 18 years of age

Venlafaxine tablets 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 tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Venlafaxine tablets 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 tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Venlafaxine tablets in this age group has not yet been demonstrated.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor should decide whether you can take Venlafaxine tablets with other medicines.

Some medicines may interact with Venlafaxine tablets and should be used with caution. 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, especially:

- Monoamine oxidase inhibitors (MAOIs: see the section "Do not take Venlafaxine tablets if you").
- ketoconazole, itraconazole, voriconazole, posaconazole, (antifungal medicines)
- haloperidol or risperidone (to treat psychiatric conditions)
- metoprolol (a beta blocker to treat high blood pressure and heart problems)
- atazanavir, nelfinavir, ritonavir, saquinavir, indinavir (antiviral medicines)
- clarithromycin, telithromycin (antibiotics)

Serotonin syndrome: a potentially life-threatening condition (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)
- medicines to treat depression, for instance SNRI, SSRI, tricyclics, or medicines containing lithium
- linezolid, an antibiotic (used to treat infections)
- moclobemide, a reversible MAOI (used to treat depression)
- sibutramine (used for weight loss)
- tramadol (a pain-killer)
- St. John's Wort (also called Hypericum perforatum, a natural or herbal remedy used to treat mild depression)
- tryptophan (used for problems such as sleep and depression)

Signs and symptoms of serotonin syndrome may include a combination of the following: restlessness, hallucinations, loss of coordination, fast heart beat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting. **Get medical care right away if you think serotonin syndrome is happening to you.**

Taking Venlafaxine tablets with food and drink

Venlafaxine tablets should be taken with food (see section 3 'How to take'). You should **avoid alcohol** while you are taking Venlafaxine tablets.

Pregnancy and breast-feeding

Tell your doctor if you become pregnant, or you are trying to become pregnant. You should use Venlafaxine tablets only after discussing the potential benefits and risks to your unborn child with your doctor.

Make sure your midwife and/or doctor know 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 new born (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.

As venlafaxine passes into breast milk, there is a risk of an effect on the baby. Therefore, you should discuss with your doctor, and decide whether you should stop breast-feeding or stop the therapy with Venlafaxine tablets.

Driving and using machines

Venlafaxine may cause confusion, dizziness and blurred vision. If you are affected, do not drive or use machinery.

Important information about some of the ingredients of Venlafaxine tablets

Venlafaxine tablets contains a sugar called **lactose**. If a doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The tablets also contain **sunset yellow** (E110) which may cause allergic reactions (see section 4 below).

Tests

Venlafaxine tablets can cause unwanted effects that you may not be aware of, such as rises in blood pressure, abnormal heart beat, slight changes in blood levels, liver enzymes or blood salt or cholesterol. In rare cases Venlafaxine can reduce the function of blood platelets leading to an increased risk of bruising or bleeding. Therefore, your doctor may wish to do blood tests, particularly if you have been taking Venlafaxine tablets for a long time.

3 How to take

Always take Venlafaxine tablets exactly as your doctor has told you. If you are not sure check with your doctor or pharmacist.

Adults aged 18 years and over

The usual recommended starting dose is 75mg per day in divided doses, two or three times a day. If needed, your doctor may increase the dose gradually up to a maximum of 375mg daily.

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

Take Venlafaxine tablets at approximately the **same time each day**, in the morning and in the evening, **with food**.

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

If you take more Venlafaxine tablets than you should

If you take more than the prescribed amount of tablets, contact your doctor or pharmacist at once.

The symptoms of a possible overdose may include a rapid heart beat, changes in level of alertness (ranging from sleepiness to coma), dilated pupils, seizures or fits, and vomiting.

If you forget to take Venlafaxine tablets

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 more in one day than the daily amount that has been prescribed for you.

If you stop taking Venlafaxine tablets

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 tablets, 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 tablets, especially when Venlafaxine tablets 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 tablets 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, Venlafaxine tablets can cause side effects, although not everybody gets them.

Allergic reactions

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

- chest tightness, wheezing, trouble swallowing or breathing
- swelling of the face, throat, hands, or feet
- feeling nervous or anxious, dizziness, throbbing sensations, sudden reddening of the skin and/or a warm feeling
- severe rash, itching, or hives (elevated patches of red or pale skin that often itch)

Serious side effects

If you notice any of the following, seek urgent medical attention:

- fast or irregular heart rate, increased blood pressure
- blurred vision, dilated pupils
- dizziness, pins and needles, movement disorder, seizures or fits
- hyperactivity and euphoria (extreme sense of well being)
- a high temperature with rigid muscles, confusion or agitation and sweating, or jerky muscle movements which you can't control (symptoms of neuroleptic malignant syndrome)

- restlessness, inability to keep still, hallucinations, loss of coordination, fast heart beat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting (serotonin syndrome)
- severe skin rashes with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome), an itchy skin rash with blood spots, bruising or discolouring of the skin, red patches (erythema multiforme) or a severe rash with reddening, peeling and swelling of the skin that resembles burns (epidermal necrolysis)
- itchy skin, yellow skin or eyes, dark urine or flu-like symptoms (symptoms of hepatitis)
- severe abdominal or back pain (which could indicate a serious problem in the gut, liver or pancreas).
- thoughts of harming or killing yourself
- coughing, wheezing, shortness of breath and a high temperature, which are symptoms of inflammation of the lungs associated with an increase in white blood cells (pulmonary eosinophilia)
- unexplained muscle pain, tenderness or weakness (rhabdomyolysis)
- treatment withdrawal effects (see section 3 'If you stop taking Venlafaxine tablets')

Tell your doctor or pharmacist if you notice any of the following side effects or notice any other effects not listed:

Very common (more than 1 in 10 users)

- headache, dry mouth (see section 2 'Dry mouth')
- nausea, sweating (including night sweats)

Common (less than 1 in 10 users)

- weight loss, decreased appetite, constipation, vomiting
- abnormal dreams, difficulty sleeping, nervousness, sedation, tremor
- confusion, feeling separated (or detached) from yourself and reality
- visual disturbances, flushing, palpitations, yawning, increased muscle tone
- difficulties passing urine, increased frequency in urination
- lack of orgasm, decreased sex drive, abnormal ejaculation/orgasm or impotence in men
- menstrual irregularities such as increased bleeding or increased irregular bleeding
- weakness, chills, increased cholesterol levels

Uncommon (less than 1 in 100 users)

- bruising, black tarry stools (faeces) or blood in stools (which can be a sign of internal bleeding), weight gain, swollen face, lips, throat or tongue, diarrhoea
- lack of feeling or emotion, hallucinations, involuntary muscle movement, agitation, grinding of the teeth
- impaired co-ordination and balance, altered taste sensation, ringing in the ears (tinnitus)
- feeling dizzy (particularly when standing up too quickly), fainting, abnormal hair loss, rash, sensitivity to sunlight
- abnormal orgasm (females)
- inability to pass urine

Frequency not known

- disorientation and confusion accompanied by hallucination (delirium), stiffness, spasms and involuntary movements of the muscles
- abnormal breast milk production, severe eye pain with decreased or blurred vision (glaucoma), excessive water intake (known as SIADH)
- decrease in blood pressure, urinary incontinence (an involuntary leakage of urine), abnormal, rapid or irregular heart beat, which could lead to fainting
- slight changes in blood levels of liver enzymes, decrease in blood sodium levels, reduced number of platelets in your blood (leading to an increased risk of bruising or bleeding) or blood disorders which may lead to an increased risk of infection
- euphoric feelings, drowsiness, dizziness, aggression, sustained rapid eye movement, clumsiness, restlessness, feeling of being drunk, sweating or rigid muscles (symptoms of serotonergic syndrome)
- skin rash, which may lead to severe blistering and peeling of the skin, itching, mild rash

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store

Keep out of the reach and sight of children.

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

There are no special storage instructions

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

6 Further information

What Venlafaxine tablets contain

- The active substance (which makes the medicine work) is venlafaxine hydrochloride. Each tablet contains either 37.5mg or 75mg of venlafaxine.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone K30, magnesium stearate, hypromellose 6CP, titanium dioxide (E171), macrogol/ PEG 400, Sunset yellow FCF lake (E110).

What Venlafaxine tablets look like and contents of the pack

Venlafaxine tablets are orange, round biconvex, film-coated tablets with the following markings:

37.5mg – V2 75mg – V4 with a scoreline.

Venlafaxine tablets come in pack sizes of 56 tablets, packed into blister packs or plastic containers

Marketing Authorisation Holder

Actavis group PTC ehf. Reykjavikurvegur 76-78, 220 Hafnarfjordur, Iceland

Manufacturer

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