

Package leaflet: Information for the patient

Venlafaxine 37.5 mg Tablets

Venlafaxine 75 mg Tablets

Venlafaxine

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

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 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 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 this medicine (listed in section 6).
- if you are also taking or have taken any time 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 other medicines, including 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 irreversible MAOI (see also the sections "Serotonin syndrome" and "Other medicines and Venlafaxine").

Warnings and precautions

Talk to your doctor or pharmacist before taking Venlafaxine

- If you use other medicines that taken concomitantly with Venlafaxine could increase the risk of developing serotonin syndrome (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 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.
- If your cholesterol levels get higher.
- 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.

Venlafaxine 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.

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 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.

Use in children and adolescents under 18 years of age

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 have 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 (MAOIs: see the section “Before you take Venlafaxine”).
- Serotonin syndrome: 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, SSRIs, tricyclics, or medicines containing lithium
 - Medicines containing linezolid, an antibiotic (used to treat infections)
 - Medicines containing moclobemide, a reversible MAOI (used to treat depression)
 - Medicines containing sibutramine (used for weight loss)
 - Medicines containing tramadol (a pain-killer)
 - 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: restlessness, hallucinations, loss of coordination, fast heart beat, 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 heart beat, 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.

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, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor 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, your baby might have some other symptoms when it is born in addition to breathing faster. They include irritability, tremor, hypotonia, constant crying, sleeping

difficulties, not feeding properly and trouble with breathing. 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 e.g. constant crying, irritability and abnormal sleep-patterns. 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.

Driving and using machines

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

Venlafaxine contains lactose

This medicine 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.

3. How to take Venlafaxine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual recommended starting dose is 75 mg per day in divided doses, two or three times a 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.

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.

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 heart beat, 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 more than the daily amount of Venlafaxine that has been prescribed for you in one day. Do not take a double dose to make up for a forgotten dose.

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 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 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 medicine, 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. **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)
- Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, fast heart beat, 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 heart beat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

Other side effects that you should tell your doctor about include:

- Coughing, wheezing, shortness of breath and a high temperature
- Black (tarry) stools or blood in stools
- Yellow skin or eyes, itchiness 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, seizures or fits
- Psychiatric problems, such as hyperactivity and euphoria (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.**Complete side effect listing**

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

- Dizziness; headache
- Nausea; dry mouth
- 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; nervousness; insomnia; abnormal dreams
- Drowsiness; tremor; pins and needles; increased muscle tone
- 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)
- Palpitations
- Increase in blood pressure; flushing;
- Yawning
- Vomiting; constipation; diarrhoea
- Increased frequency in urination; difficulties passing urine

- Menstrual irregularities such as increased bleeding or increased irregular bleeding; abnormal ejaculation/orgasm (males); erectile dysfunction (impotence)
- Weakness (asthenia); fatigue; chills
- Increased cholesterol

Uncommon (may affect up to 1 in 100 people)

- Hallucinations; feeling separated (or detached) from reality; agitation; abnormal orgasm (females); lack of feeling or emotion; feeling over-excited; grinding of the teeth
- A sensation of restlessness or an inability to sit or stand still; fainting; involuntary movements of the muscles; impaired coordination and balance; altered taste sensation
- Fast heart beat; feeling dizzy (particularly when standing up too quickly)
- Shortness of breath
- Vomiting blood, black tarry stools (faeces) or blood in stools; which can be a sign of internal bleeding
- General swelling of the skin especially the face, mouth, tongue, throat area or hands and feet and/or a raised itchy rash (hives) may be present; sensitivity to sunlight; bruising; rash; abnormal hair loss
- Inability to pass urine;
- Weight gain; weight loss

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

- Seizures or fits
- Inability to control urination
- Over activity, racing thoughts and decreased need for sleep (mania)

Not known (frequency cannot be estimated from available data)

- Reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding; blood disorders which may lead to an increased risk of infection
- Swollen face or tongue, shortness of breath or difficulty breathing, often with skin rashes (this may be a serious allergic reaction)
- Excessive water intake (known as SIADH)
- Decrease in blood sodium levels
- 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)
- Disorientation and confusion often accompanied by hallucination (delirium); aggression
- A high temperature with rigid muscles, confusion or agitation, and sweating, or if you experience jerky muscle movements which you can't control, these may be symptoms of serious conditions known as neuroleptic malignant syndrome; euphoric feelings, drowsiness, sustained rapid eye movement, clumsiness, restlessness, feeling of being drunk, sweating or rigid muscles, which are symptoms of serotonin syndrome; stiffness, spasms and involuntary movements of the muscles
- Severe eye pain and decreased or blurred vision
- Vertigo
- Decrease in blood pressure; abnormal, rapid or irregular heart beat, which could lead to fainting; 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)
- 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)
- 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); slight changes in blood levels of liver enzymes
- Skin rash, which may lead to severe blistering and peeling of the skin; itching; mild rash
- Unexplained muscle pain, tenderness or weakness (rhabdomyolysis)
- Abnormal breast milk production

Venlafaxine 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Venlafaxine

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 after EXP. The expiry date refers to the last day of that month.

Venlafaxine 37.5 mg:

This medicinal product does not require any special storage conditions (tablet container and blister)

Venlafaxine 75 mg:

This medicinal product does not require any special storage conditions (tablet container and blister)

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 contains

- The active substance is venlafaxine

Venlafaxine 37.5 mg:

One tablet contains 37.5 mg venlafaxine as venlafaxine hydrochloride.

Venlafaxine 75 mg:

One tablet contains 75 mg venlafaxine as venlafaxine hydrochloride.

- The other ingredients are microcrystalline cellulose, lactose monohydrate, sodium starch glycolate (type A), magnesium stearate, anhydrous, colloidal silicon dioxide, brown ferric oxide (E172).

What Venlafaxine looks like and contents of the pack

Venlafaxine 37.5 mg: Pale, red-brown or brownish, oblong tablet coded 3.

Venlafaxine 75 mg: Pale, red-brown or brownish, oblong tablet, scored and coded 7 on each half. The tablet can be divided into two equal doses.

Polyethylene tablet container and closure (tamper evident)

Pack sizes: 28, 30, 42, 50, 56, 60, 90, 98, 100, 250 tablets

Blister (Al/PVC)

Pack sizes: 10, 14, 15, 20, 28, 30, 42, 45, 50, 56, 60, 90, 98, 98x1, 100, 100x1, 250 tablets

Not all package sizes or types may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, D-39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, SI-1526 Ljubljana, Slovenia.

Lek S.A., Ul. Podlipie 16, 95-010 Stryków, Poland.

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden	Venlafaxin Sandoz 25 mg tablett Venlafaxin Sandoz 37,5 mg tablett Venlafaxin Sandoz 50 mg tablett Venlafaxin Sandoz 75 mg tablett Venlafaxin Sandoz 150 mg tablett
Austria	Venlafaxin Sandoz 50 mg - Tabletten
Germany	Venlafaxin HEXAL 37,5 mg Tabletten Venlafaxin HEXAL 75 mg Tabletten
Ireland	Venlafaxine 37.5 mg Tablets Venlafaxine 75 mg Tablets
Iceland	Venlafaxin Sandoz 37,5 mg töflur
Spain	Venlafaxina Sandoz 37,5 mg comprimidos EFG Venlafaxina Sandoz 50 mg comprimidos EFG Venlafaxina Sandoz 75 mg comprimidos EFG

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