

Vedixal 37.5 mg Tablets & 75 mg Tablets

venlafaxine (as hydrochloride)

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 or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

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

1 What Vedixal is and what it is used for

Vedixal 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.

Vedixal 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 Vedixal

Do not take Vedixal

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

Warning and precautions

Talk to your doctor or pharmacist before taking Vedixal

- if you use other medicines that taken together with Vedixal could increase the risk of developing serotonin syndrome (see the section “Other medicines and Vedixal”)
- 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 i.e. **warfarin** or other blood-thinning medicines
- if you are pregnant (see Pregnancy and breast-feeding)
- 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.

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

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

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

Do not drink alcohol while being treated with Vedixal 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 an anxiety disorder, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting 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 or harming yourself
- if you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years 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 Vedixal. Therefore, the dosage of the diabetes medicines may need to be adjusted.

Use in children and adolescents under 18 years of age

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

Other medicines and Vedixal

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Your doctor should decide whether you can take Vedixal with other medicines.

Do not start or stop taking any medicines, including those bought without a prescription and 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 Vedixal**. 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 Vedixal").
- 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)
- Other 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 **MAOI** (used to treat depression)
- Medicines containing **sibutramine** (used for weight loss)
- Medicines containing **opioids (e.g., buprenorphine, tramadol, fentanyl, tapentadol, pethidine, or pentazocine)** used to treat severe pain
- 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: restlessness, hallucinations, loss of co-ordination, 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).

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 Vedixal 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).

Vedixal with food, drink and alcohol

Vedixal should be taken with food (see section 3 “How to take Vedixal”).

Do not drink alcohol while being treated with Vedixal. Concomitant use with alcohol can lead to extreme tiredness and unconsciousness and can make your symptoms of depression and other conditions, such as anxiety disorders worse.

Pregnancy and breast-feeding

Tell your doctor if you become pregnant, or you are trying to become pregnant. You should use Vedixal 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 Vedixal. 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 this medicine during pregnancy, other symptoms your baby might have when it is born is not feeding properly, in addition to having trouble 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.

If you take Vedixal 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 Vedixal so they can advise you.

Vedixal 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 breastfeeding or stop the therapy with Vedixal.

Driving and using machines

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

Vedixal 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.

Vedixal contains sodium

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

3 How to take Vedixal

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 37.5 mg twice daily or 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 Vedixal at approximately the same time each day, in the morning and in the evening.

Vedixal should be taken with food.

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

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

Use in children and adolescents under 18 years of age

Vedixal should normally not be used for children and adolescents under 18 years.

If you take more Vedixal than you should

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

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

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 Vedixal

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 Vedixal that has been prescribed for you in one day.

If you stop taking Vedixal

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 Vedixal, he/she may ask you to reduce your dose slowly, before stopping treatment altogether. Side effects are known to occur when people stop using Vedixal, especially when Vedixal 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, flu-like symptoms, problems with eyesight and increase in blood pressure (which can cause headache, dizziness, ringing in the ear, sweating etc).

Your doctor will advise you on how you should gradually discontinue Vedixal 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 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 you notice any of the following side-effects, stop taking Vedixal immediately. **Tell your doctor or go to the casualty department at your nearest hospital straightaway.**

- 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 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).

- Stress cardiomyopathy (takotsubo cardiomyopathy), which may include chest pain, shortness of breath, dizziness, fainting, irregular heartbeat.

Other side effects that you should **tell your doctor about**

- 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

- Treatment withdrawal (see the section “How to take Vedixal, If you stop taking Vedixal”)
- Prolonged bleeding - If you cut or injure yourself, it may take slightly longer than usual for bleeding to stop.

Other possible side-effects

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

- Dizziness; headache
- Nausea; dry mouth
- Sweating (including night sweats)
- Constipation
- Insomnia
- Sedation.

Common (may affect up to 1 in 10 people)

- Appetite decreased
- Confusion; feeling separated (or detached) from yourself; lack of orgasm; decreased libido
- Nervousness; abnormal dreams, agitation
- Tremor; pins and needles; 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)
- Increase in blood pressure; flushing
- Yawning
- Vomiting; diarrhoea
- Increased frequency in urination; difficulties passing urine; inability to pass urine
- Menstrual irregularities such as increased bleeding or increased irregular bleeding; abnormal ejaculation/orgasm (males); erectile dysfunction (impotence)
- Weakness (asthenia); fatigue; chills
- Increased cholesterol
- A sensation of restlessness or an inability to sit or stand still
- Abnormal sensation such as tingling, tickling, pricking, numbness or burning of the skin; rash; itchiness
- Altered taste sensation
- Fast heartbeat; palpitations
- Shortness of breath
- Weight gain; weight loss.

Uncommon (may affect up to 1 in 100 people)

- Feeling separated (or detached) from reality; hallucination; abnormal orgasm; lack of feeling or emotion; feeling over-excited; grinding of the teeth
- Over activity, racing thoughts and decreased need for sleep (mania)
- Fainting; involuntary movements of the muscles; impaired coordination and balance
- Feeling dizzy (particularly when standing up too quickly)
- 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 control urination
- Seizures or fits

- Decrease in blood pressure
- Slight changes in blood levels of liver enzymes.

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

- 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; reduced number of red blood cells, white blood cells, and platelets
- Decrease in blood sodium levels
- 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
- Convulsion
- Unexplained muscle pain, tenderness or weakness (rhabdomyolysis)
- Disorientation and confusion often accompanied by hallucination (delirium)
- Severe abdominal or back pains (which could indicate a serious problem in the gut, liver or pancreas)
- Decrease in blood pressure; abnormal, rapid or irregular heartbeat, 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)
- 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
- 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)
- 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)
- Neuroleptic Malignant Syndrome (NMS) or Serotonin Syndrome with symptoms such as restlessness, hallucinations, loss of co-ordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting, fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test)
- Severe eye pain and decreased or blurred vision
- Decrease in blood pressure; abnormal, rapid or irregular heartbeat, which could lead to fainting
- Coughing, wheezing, shortness of breath
- Skin rashes or redness, which may develop into life-threatening skin reactions including widespread rash with blisters and peeling skin, particularly occurring around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), extensive peeling of the skin (more than 30% of the body surface –toxic epidermal necrolysis)
- Rash, skin lesions.

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

- Reduced number of platelets in your blood
- Abnormal breast milk production
- Stiff, jerky movements of your face and body that you can't control
- It takes longer than usual for bleeding to stop
- Mucosal bleeding.

Not known: frequency 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 Vedixal)

- Aggression
- Vertigo
- Stress cardiomyopathy (takotsubo cardiomyopathy), which may include chest pain, shortness of breath, dizziness, fainting, irregular heartbeat
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy and breast-feeding in section 2 for more information.

Vedixal 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 or liver enzymes, sodium or cholesterol. More rarely, Vedixal 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 Vedixal for a long time. 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.

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; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Vedixal

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 packaging. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions.

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 Vedixal contains

- The active substance is venlafaxine hydrochloride.

Vedixal 37.5 mg: Each tablet contains 37.5 mg venlafaxine as venlafaxine hydrochloride.

Vedixal 75 mg: Each tablet contains 75 mg venlafaxine as venlafaxine hydrochloride.

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

What Vedixal looks like and contents of the pack

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

Vedixal 75 mg: Pale, red-brown or brownish, oblong tablet, scored and coded 7 on each half.

The tablet can be divided into two equal halves.

Blister (Al/PVC)

Pack sizes: 28 and 56

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co Cork.

Manufacturers

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

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

Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

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