

Package leaflet: Information for the user

Vedixal XL 75 mg prolonged-release capsules, hard Vedixal XL 150 mg prolonged-release capsules, hard

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

1. What Vedixal XL is and what it is used for

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

2. What you need to know before you take Vedixal XL

Do not take Vedixal XL

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

Warnings and precautions

Talk to your doctor or pharmacist **before** taking Vedixal XL:

- If you use other medicines that taken together with Vedixal XL could increase the risk of developing serotonin syndrome (see the section “Other medicines and Vedixal XL”).
- 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 pregnant see ‘Pregnancy and breast-feeding’), 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.

Vedixal XL 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.

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

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These 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 Vedixal XL.

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 Vedixal XL. Therefore, the dosages of your diabetes medicines may need to be adjusted.

Sexual problems

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

Children and adolescents

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

Other medicines and Vedixal XL

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 Vedixal XL 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 Vedixal XL**. 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 XL").

- **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, 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)
- buprenorphine-containing medical products. These medicines may interact with Vedixal XL and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations,

coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

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.

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 XL 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 XL with food, drink and alcohol

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

Do not drink alcohol while being treated with Vedixal XL. 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

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 Vedixal XL 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 XL. 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, 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.

If you take Vedixal XL 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 XL so they can advise you.

Vedixal XL 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 this medicine.

Driving and using machines

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

Vedixal XL capsules contain sugar spheres, containing sucrose. If you have been told by your doctor that you have an intolerance for some sugars, contact your doctor before taking this medicinal product.

Vedixal XL contains Sodium

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

3. How to take Vedixal XL

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

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

Vedixal XL should be taken with food.

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

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

If you take more Vedixal XL than you should

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

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

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 Vedixal XL

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 Vedixal XL that has been prescribed for you in one day.

If you stop taking Vedixal XL

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 XL, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using this medicine, especially when it is stopped suddenly or the dose is reduced too quickly. Some patients may experience symptoms such as 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 Vedixal XL 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, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, do not take more Vedixal XL. **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 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).
- Signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms. This may be the result of a blood disorder which leads to an increased risk of infection.
- Severe rash, which may lead to severe blistering and peeling of the skin.
- Unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.

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

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

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

- Coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- Black (tarry) stools or blood in stools

- 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 Vedixal XL, if you stop taking Vedixal XL”).
- Prolonged bleeding – if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop.

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

Other side effects that may occur

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

- 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)

- 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 XL)
- Aggression
- Vertigo
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy and breast-feeding in section 2 for more information.

Vedixal XL 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 of liver enzymes, sodium or cholesterol. More rarely, Vedixal XL 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 XL 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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 Earlsfort Terrace
 IRL - Dublin 2
 Tel: +353 1 6764971
 Fax: +353 1 6762517
 Website: www.hpra.ie
 e-mail: medsafety@hpra.ie.

5. How to store Vedixal XL

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 Blister, bottle label and carton after EXP. The expiry date refers to the last day of that month.

This medicine 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 XL contains

- The active substance is venlafaxine.

Each prolonged-release capsule contains 75 mg of venlafaxine (as hydrochloride).

Each prolonged-release capsule contains 150 mg of venlafaxine (as hydrochloride).

Other ingredients in the capsules are: Sugar spheres (containing sucrose), hypromellose, talc and ethyl cellulose.

The capsule shell contains:

Cap: Gelatine, iron oxide red (E172), titanium dioxide (E171) and sodium lauryl sulphate.

Body: Gelatin, iron oxide red (E172), titanium dioxide (E171), sodium lauryl sulfate.

The printing ink contains: Shellac and black iron oxide (E172).

What Vedixal XL looks like and contents of the pack

Prolonged-release capsule, hard.

Venlafaxine 75 mg prolonged-release capsules, hard

White to off-white spherical to oval pellets filled in Empty hard gelatin capsule shell (size '1') of Opaque Peach color cap and Opaque Peach color body imprinted with "E" on cap and "74" on the body with edible black ink.

Venlafaxine 150 mg prolonged-release capsules, hard

White to off-white spherical to oval pellets filled in Empty hard gelatin capsule shell (size '0') of Opaque Dark orange color cap and Opaque Dark orange color body imprinted with "E" on cap and "89" on the body with edible black ink.

Venlafaxine capsules are available in
Clear PVC/PE/PVDC-Aluminium foil:

Venlafaxine 75 mg/150 mg: 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 98 and 100 capsules

HDPE Bottle with polypropylene closure:

Venlafaxine 75 mg/150 mg: 30, 100 and 500 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Floriana FRN 1913
Malta

Manufacturer

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