

Package leaflet: Information for the user

Venex XL 37.5mg Prolonged-release Capsules, hard Venex XL 75mg Prolonged-release Capsules, hard Venex XL 150mg 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 Venex XL is and what is used for
2. What you need to know before you take Venex XL
3. How to take Venex XL
4. Possible side effects
5. How to store Venex XL
6. Contents of the pack and other information

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

Venex XL contains the active substance venlafaxine.

Venex 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.

Venex 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 Venex XL

DO NOT take Venex 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 Venex XL, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Venex XL before you take any MAOI (see also the section entitled "Other medicines and Venex XL" and the information in that section about "Serotonin syndrome")

Warnings and precautions

Talk to your doctor or pharmacist **before** taking Venex XL if you:

- use other medicines that taken together with Venex XL could increase the risk of developing serotonin syndrome (see the section "Other medicines and Venex XL")
- 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 been told you have an abnormal heart rhythm
- 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 pregnant (see ‘Pregnancy’)
- are taking other medicines that may increase the risk of bleeding e.g., warfarin (used to prevent blood clots)
- 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

Venex 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.

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

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

Children and adolescents

Venex 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 Venex 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 Venex XL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor will decide whether you can take Venex 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 Venex 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 Venex 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 include medicines containing:
 - triptans (used for migraine)
 - lithium or other medicines to treat depression, for instance SNRIs, SSRIs, tricyclics
 - linezolid, an antibiotic (used to treat infections)
 - moclobemide, a MAOI (used to treat depression)
 - sibutramine (used for weight loss)
 - tramadol, fentanyl, tapentadol, pethidine, or pentazocine (used to treat severe pain)
 - dextromethorphan (used to treat coughing)
 - methadone (used to treat opioid drug addiction or severe pain)
 - methylene blue (used to treat high levels of methaemoglobin in the blood)
 - 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)
 - 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 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.

Other medicines and Venex XL continued

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 Venex 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)

Venex XL with food, drink and alcohol

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

You should avoid alcohol while you are taking Venex XL.

Pregnancy and breast-feeding

Pregnancy

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 Venex 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 Venex 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 Venex 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 Venex XL so they can advise you.

Breast-feeding

Venex 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.

Venex XL 150 mg contains sodium and the colourants sunset yellow FCF (E110) and allura red AC (E129)

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'. Sunset yellow FCF (E110) and allura red AC (E129) may cause allergic reactions.

3. How to take Venex XL

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

Dosage

Depression

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

Panic disorder

Your doctor will start with a lower dose (37.5 mg) and then increase the dose gradually. The maximum dose is 225 mg/day.

Generalised anxiety disorder or social anxiety disorder

The recommended starting dose is 75 mg per day. The maximum dose is 225 mg/day.

Kidney or liver problems

Talk to your doctor, since your dose of this medicine may need to be different.

Method of administration

Take Venex 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.

Venex XL should be taken with food.

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

If you take more Venex XL than you should

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

The symptoms of a possible overdose may include a rapid heartbeat, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

If you forget to take Venex 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 Venex XL that has been prescribed for you in one day.

If you stop taking Venex 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 Venex 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 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 Venex XL 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.

Serious side effects

If any of the following happen, do not take more Venex 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 rash, itching, or hives (elevated patches of red or pale skin that often itch)
- signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting.

In its most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test)

- signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms. This may be the result of a blood disorder which leads to an increased risk of infection.

- severe rash, which may lead to severe blistering and peeling of the skin.
- unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.

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 Venex XL - If you stop taking Venex XL")
- prolonged bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop

Other side effects that may occur

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

- dizziness, headache, drowsiness
- insomnia
- nausea, dry mouth, constipation
- sweating (including night sweats)

Common (may affect up to 1 in 10 people)

- appetite decreased
- confusion, feeling separated (or detached) from yourself, lack of orgasm, decreased libido, agitation, nervousness, abnormal dreams
- tremor; a sensation of restlessness or an inability to sit or stand still, pins and needles, altered taste sensation, increased muscle tonus
- visual disturbance including blurred vision, dilated pupils, inability of the eye to automatically change focus from distant to near objects
- ringing in the ears (tinnitus)
- fast heartbeat, palpitations
- increase in blood pressure, flushing
- shortness of breath, yawning
- vomiting, diarrhoea
- mild rash, itching
- increased frequency in urination, inability to pass urine, difficulties passing urine
- menstrual irregularities such as increased bleeding or increased irregular bleeding, abnormal ejaculation/orgasm (males), erectile dysfunction (impotence)
- weakness (asthenia), fatigue, chills
- weight gain, weight loss
- increased cholesterol

Uncommon (may affect up to 1 in 100 people)

- over activity, racing thoughts and decreased need for sleep (mania)
- hallucinations; feeling separated (or detached) from reality; abnormal orgasm; lack of feeling or emotion; feeling over-excited; grinding of the teeth
- fainting; involuntary movements of the muscles; impaired coordination and balance
- feeling dizzy (particularly when standing up too quickly); decrease in blood pressure
- vomiting blood, black tarry stools (faeces) or blood in stools - which can be a sign of internal bleeding
- sensitivity to sunlight; bruising; abnormal hair loss
- inability to control urination
- stiffness, spasms and involuntary movements of the muscles

- slight changes in blood levels of liver enzymes

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

- seizures or fits
- coughing, wheezing and shortness of breath which may be accompanied by a high temperature
- disorientation and confusion often accompanied by hallucination (delirium)
- excessive water intake (known as SIADH)
- decrease in blood sodium levels
- severe eye pain and decreased or blurred vision
- abnormal, rapid or irregular heartbeat, which could lead to fainting
- severe abdominal or back pains (which could indicate a serious problem in the gut, liver or pancreas)
- itchiness, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis)

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

- prolonged bleeding, which may be a sign of reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding
- abnormal breast milk production
- unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins)

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 Venex XL – Warnings and Precautions”)
- aggression
- vertigo
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see ‘Pregnancy’ in section 2 for more information

Blood tests

Venex 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, Venex 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 Venex XL 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 the national reporting system:

For Ireland:

HPRA Pharmacovigilance

Website: www.hpra.ie

For Malta:

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Venex 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 and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if your capsules appear to be significantly discoloured or show any other signs of major deterioration.

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 Venex XL contains

The active substance is venlafaxine.

Venex XL 37.5 mg prolonged-release capsules, hard:

Each capsule contains 42.45 mg venlafaxine hydrochloride equivalent to 37.5 mg venlafaxine

Venex XL 75 mg prolonged-release capsules, hard:

Each capsule contains 84.9 mg venlafaxine hydrochloride equivalent to 75 mg venlafaxine

Venex XL 150 mg prolonged-release capsules, hard:

Each capsule contains 169.8 mg venlafaxine hydrochloride equivalent to 150 mg venlafaxine

The other ingredients are:

Core:

Microcrystalline Cellulose (E460)

Povidone

Talc (E553b)

Silica, colloidal anhydrous (E551)

Magnesium stearate (E572)

Film coating:

Ethyl Cellulose

Copovidone

Venex XL 37.5 mg:

Capsule Cap:

Black iron oxide (E172)

Red iron oxide (E172)

Yellow iron oxide (E172)

Titanium dioxide (E171)

Gelatin

Capsule body:

Black iron oxide (E172)

Red iron oxide (E172)

Titanium dioxide (E171)

Gelatin

Red Ink (composition: shellac, propylene glycol, strong ammonia solution and red iron oxide (E 172))

Venex XL 75 mg:

Capsule Cap:

Black iron oxide (E172), Red iron oxide (E172), Titanium dioxide (E171), Gelatin

Capsule body

Black iron oxide (E172), Red iron oxide (E172), Titanium dioxide (E171), Gelatin

Red ink (composition: shellac, propylene glycol, strong ammonia solution and red iron oxide (E172))

Venex XL 150 mg:

Capsule Cap:

Brilliant blue FCF (E133), Allura red AC (E129), Sunset yellow FCF (E110), Titanium dioxide (E171), Gelatin

Capsule body:

Brilliant blue FCF (E133), Allura red AC (E129), Sunset yellow FCF (E110), Titanium dioxide (E171), Gelatin

White ink (composition: shellac, propylene glycol, sodium hydroxide, povidone, titanium dioxide (E171))

What Venex XL looks like and contents of the pack

Venex XL 37.5 mg prolonged-release capsules, hard:

Light grey opaque / peach opaque, size '3' hard gelatin capsules having thick and thin radial circular band on the body in red ink and thick and thin radial circular band on the cap in red ink. The capsule is filled with 3 white to off-white, round, biconvex, film-coated mini tablets of 12.5 mg each.

Venex XL 75 mg prolonged-release capsules, hard:

Peach opaque / peach opaque, size '1' hard gelatin capsules having thick and thin radial circular band on the body in red ink and thick and thin radial circular band on the cap in red ink. The capsule is filled with 6 white to off-white, round, biconvex, film coated mini tablets of 12.5 mg each.

Venex XL 150 mg prolonged-release capsules, hard:

Dark orange / dark orange opaque, size '0' hard gelatin capsules having thick and thin radial circular band on the body in white ink and thick and thin radial circular band on the cap in white ink. The capsule is filled with 12 white to off-white, round, biconvex, film coated mini tablets of 12.5 mg each.

The prolonged-release capsules are available in packs of 28 prolonged-release capsules, packed in PVC/Aclar film and aluminium blister lidding foil and white opaque PVC/PVDC.

Venex XL 37.5 mg prolonged-release capsules, hard:

7, 10, 14, 20, 28, 30, 50, 56, 98 and 100 capsules packed in blisters (PVC/ACLAR film and Aluminium lidding foil or aluminium foil and White Opaque PVC/PVdC film).

Not all pack sizes may be marketed.

Venex XL 75 mg prolonged-release capsules, hard:

7, 10, 14, 20, 28, 30, 50, 56, 98, 100, 105 and 120 capsules packed in blisters (PVC/ACLAR film and Aluminium lidding foil or aluminium foil and White Opaque PVC/PVdC film).

Not all pack sizes may be marketed.

Venex XL 150 mg prolonged-release capsules, hard:

10, 14, 20, 28, 30, 50, 56, 98, 100, 105 and 120 capsules packed in blisters (PVC/ACLAR film and Aluminium lidding foil or aluminium foil and White Opaque PVC/PVdC film).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany

Centrafarm Services B.V., Nieuwe Donk 9, NL- 4879 AC Etten-Leur, The Netherlands

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

NL: Venlafaxine CF 37,5 mg, 75 mg, 150 mg, harde capsules met verlengde afgifte

BE: Venlafaxine EG 37,5 mg, 75 mg, 150 mg harde capsules met verlengde afgifte

DE: Venlafaxin AL 37,5 mg, 75 mg, 150 mg Hartkapseln, retardiert
DK: Efastad, hårde depotkapsler
ES: Venlafaxina Retard STADAGEN 37,5 mg, 75 mg, 150 mg cápsulas duras de liberación prolongada EFG
FR: VENLAFAXINE EG LABO LP 37,5 mg, 75 mg, gélule à libération prolongée
IE: Venex XL 37.5 mg, 75 mg, 150 mg prolonged-release capsules, hard
LU: Venlafaxine EG 37,5mg, 75 mg, 150 mg gélules à libération prolongée
MT: Venex XL 37.5 mg, 75 mg, 150 mg prolonged-release capsules, hard
PT: Venlafaxina Ciclum
SE: Efastad 37,5 mg, 75 mg, 150 mg depotkapsel, hård

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