

PACKAGE LEAFLET

Package leaflet: Information for the user

Venlablue XL 75 mg prolonged release capsules, hard **Venlablue 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 or nurse.
- 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 Venlablue XL is and what it is used for
2. What you need to know before you take Venlablue XL
3. How to take Venlablue XL
4. Possible side effects
5. How to store Venlablue XL
6. Contents of the pack and other information

1. What Venlablue XL and what it is used for

Venlablue XL is an antidepressant that belongs to a group of medicines called serotonin and noradrenaline reuptake inhibitors (SNRIs). This group of medicines is used to treat depression and other conditions such as anxiety disorders. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

Venlablue XL is a treatment for adults with depression. Venlablue XL is also a treatment for adults with social anxiety disorder (fear or avoidance of social situations). 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 Venlablue XL

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Venlablue XL

- If you use other medicines that taken concomitantly with Venlablue XL could increase the risk of developing serotonin syndrome, a potentially life-threatening condition (see the section "Other medicines and Venlablue 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 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 breastfeeding') 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.

Talk to your doctor or pharmacist before using Venlafaxine Bluefish, especially if you get:

- Serotonin syndrome (excessive serotonin levels caused by increased nerve cell activity)
- Neuroleptic Malignant Syndrome (one has symptoms such as fever, muscular rigidity, altered mental status and autonomic dysfunction).

These conditions can occur with:

- Other serotonergic agents (essentially antidepressants, e.g. SSRIs, SNRIs and triptans).
- MAO-inhibitors (substances used to treat depression, e.g. methyleneblue).
- Antipsychotics (substances used to treat schizophrenia and bipolar disorder).

Careful monitoring of the patient is advised throughout treatment, especially when combining agents with venlafaxine; this combination can have an adverse effect on serotonin and dopamine levels.

Venlablue 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 Venlablue 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 may be increased when you 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 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.

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

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 Venlablue XL. Therefore, the dosages of our diabetes medicines may need to be adjusted.

Children and adolescents

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

Other medicines and Venlablue 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 Venlablue 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 Venlablue XL**. Tell your doctor if you have taken these medicines within the last 14 days. (MAOIs: see the section "Before you take Venlablue 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 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, 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) or buprenorphine (used to treat opioid drug addiction or moderate 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 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.

The following medicines may also interact with Venlablue 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)

Venlablue XL with food, drink and alcohol

Venlablue XL should be taken with food (See section 3).

Do not drink alcohol while being treated with Venlablue 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 for advice before taking this medicine. You should use Venlablue 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 Venlablue XL. When taking 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 Venlablue XL during pregnancy, other symptoms your baby might have when it is born is not feeding properly, in addition to having trouble breathing. They include 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.

If you take Venlafaxine Bluefish 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 Venlafaxine Bluefish so they can advise you.

Venlablue 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 Venlablue XL.

Driving and using machines

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

Venlablue XL 150 mg contains allura red (E129), sunset yellow FCF (E110) and brilliant blue FCF (E133) which may cause allergic reactions

3. How to take Venlablue 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 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. The maximum dose for social anxiety disorder is 225 mg/day.

Take Venlablue 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. Chewing, crushing or dissolving the content of the capsule may damage the film coating that modifies the release of the drug.

Venlablue XL should be taken with food.

Patients with liver and kidney problems:

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

Do not stop taking Venlablue XL without talking to your doctor (see the section “If you stop taking Venlablue XL”).

If you take more Venlablue XL than you should

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

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

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 Venlablue 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 .

If you stop taking Venlablue 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 Venlablue XL he/she will 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 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 Venlablue 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.

If any of the following happen, do not take more Venlablue XL. 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 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).

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).
- Treatment withdrawal (see the section “How to take Venlablue XL, if you stop taking Venlablue 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 granules or balls in your stools after taking Venlablue XL. Inside Venlablue XL capsules are spheroids or small white balls that contain the venlafaxine active ingredient. These spheroids are released from the capsule into your gastrointestinal tract. As the spheroids travel the length of your gastrointestinal tract, venlafaxine is slowly released. The spheroid “shell” remains undissolved and is eliminated in your stools. Therefore, even though you may see spheroids in your stools, your dose of venlafaxine has been absorbed.

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 heartbeat; 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)

Frequency not known(frequency cannot be estimated from the 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, Before you take Venlablue XL)
- 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 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)
- 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
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy and breast-feeding in section 2 for more information

Venlablue 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 or liver enzymes, sodium or cholesterol. More rarely, Venlablue 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 Venlablue 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 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 Venlablue 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 carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not use this medicine if you notice that the capsules are sticky.

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 to protect the environment.

6. Content of the pack and other information

What Venlablue XL contains

The active substance is venlafaxine.

Each Venlablue XL 75 mg capsule contains: venlafaxine hydrochloride, corresponding to 75 mg venlafaxine.

Each Venlablue XL 150 mg capsule contains: venlafaxine hydrochloride, corresponding to 150 mg venlafaxine.

The other ingredients are

Tablet core:

microcrystalline cellulose, povidone, talc, silica, colloidal anhydrous, magnesium stearate

Tablet film coat:

ethyl cellulose, copovidone

75 mg:

Capsule:

black iron oxide (E172), red iron oxide (E172), titanium dioxide (E171), gelatin

Printing Inks:

Shellac, red iron oxide

150 mg:

Capsule:

allura red (E129), sunset yellow FCF (E110), brilliant blue FCF (E133), titanium dioxide (E171), gelatin

Printing Inks:

Shellac, titanium dioxide

What Venlablue XL looks like and contents of the pack

Prolonged release capsule, hard

75 mg: 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.

150 mg: 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.

Blister packs of PVC/Aclar film and aluminium foil; 10, 14, 28, 30, 50& 100 capsules
Blister packs of PVC/PVdC film and aluminium foil; 10, 14, 28, 30, 50& 100 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of the medicinal product
AT	Venlafaxin Bluefish 75 mg/150 mg Hartkapseln, retardiert
DE	Venlafaxin Bluefish 75/150 mg Hartkapseln, retardiert
DK	Venlafaxin Bluefish XR 75 mg/150 mg
ES	Venlafaxina Bluefish 75 mg/150 mg Cápsulas de liberación prolongada
FI	Venlafaxine Bluefish 75 mg/150 mg depotkapseli, kova Venlafaxine Bluefish 75 mg/150 mg depotkapsel, hård
FR	Venlafaxine Bluefish LP 37.5 mg/75 mg/150 mg gélules à libération prolongée
IE	Venlablue XL 75 mg/150 mg prolonged release capsules, hard
IT	Venlafaxina ABC 75 mg/150 mg Capsule a rilascio prolungato
NO	Venlafaxine Bluefish XR
PL	Venlafaxine Bluefish XL
PT	Venlafaxina Bluefish XR
SE(RMS)	Venlafaxine Bluefish 37.5 mg/75 mg/150 mg depotkaplar, hårda
UK(NI)	Venlablue XL 37.5mg/75 mg/150 mg prolonged-release capsules, hard
IS	Venlafaxine Bluefish 37,5 mg/75 mg/150 mg hart forðahylki.

This leaflet was last revised in