Package leaflet: Information for the user

Venlasov XL 37.5 mg Prolonged-Release Capsules

venlafaxine hydrochloride

IMPORTANT THINGS YOU SHOULD KNOW ABOUT VENLASOV XL
Please read all of this leaflet before you start to take your medicine as it contains important information about Venlasov XL.

- **Venlasov XL is used to treat depression, severe and persistent anxiety known as generalised anxiety disorder (GAD), social anxiety disorder (also known as social phobia) and panic disorder (panic attacks)**

- **Venlasov XL is not for use in children and adolescents –** see section 2 'Use in children and adolescents'.

If you have any concerns about how you feel, or about this medication, it is important that you talk to your doctor - even if you feel anxious or worried about doing so. You may find it helpful to tell a friend or relative that you are depressed or suffering from an anxiety disorder, and that you have been prescribed this medication; it might be useful to show them this leaflet.

- **Venlasov XL may not start to work immediately.** Some people taking antidepressants may feel worse before feeling better. Your doctor may ask to see you again a couple of weeks after starting your treatment and then regularly until you start to feel well again. Tell your doctor if you do not start to feel better.

- **Some people who are depressed may think of harming or killing themself. If this happens you should see your doctor or go to a hospital straight away** – see in section 2 'Thoughts of suicide and worsening of your depression or anxiety disorder'

- **If you take too many capsules it is important to seek immediate medical attention, even if you feel well, because of the risk of serious side effects**

- **Do not stop taking Venlasov XL or change your dose without the advice of your doctor even if you feel better.** If you stop taking Venlasov XL abruptly you may get withdrawal reactions – see in section 3 'If you stop taking Venlasov XL'

- **If you have heart problems such as fast or irregular heart rate or high blood pressure you should talk to your doctor before taking Venlasov XL** – see in section 2 'What you need to know before you take Venlasov XL'

- **Taking certain other medicines with Venlasov XL may cause problems. You should tell your doctor if you are taking any other medicines** – see in section 2 'What you need to know before you take Venlasov XL'

- **See your doctor without delay** if you feel restless and feel like you can't keep still, feel 'high' or very over-excited, have jerky muscle movements which you can't control. See section 4 – 'Possible side effects' for other important information

If you are pregnant, or intend to become pregnant, or breast-feeding, you should talk to your doctor – see section 2 'Pregnancy and breast-feeding'
More information on all of these points is provided in the rest of this leaflet.

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

1. What Venlasov XL Capsules are and what they are used for

The name of this medicine is Venlasov XL 37.5 mg Prolonged-Release Capsules (referred to as Venlasov XL Capsules throughout this leaflet).

Venlasov XL Capsules contain the active ingredient venlafaxine hydrochloride. Venlasov XL Capsules are 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 not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

Venlasov XL Capsules are 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 Venlasov XL Capsules

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Venlasov XL Capsules
• if you use other medicines that taken together with Venlasov XL Capsules could increase the risk of developing serotonin syndrome (see the section 'Other medicines and Venlasov XL Capsules').
• 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 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.

This medicine 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 Venlasov XL Capsules 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 Venlasov XL Capsules.

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 dental caries (tooth decay). Therefore, you should take special care with your dental hygiene.

Diabetes
Your blood glucose levels may be altered due to Venlasov XL Capsules. Therefore, the dosage of your diabetes medicines may need to be adjusted.

If any of these apply to you, or if you are not sure, tell your doctor.

Sexual problems
Medicines like Venlasov XL Capsules (so called SNRI's) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Use in children and adolescents
Venlasov XL Capsules 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 Venlasov XL Capsules.
- 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 Venlasov XL Capsules
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 Venlasov XL Capsules 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 Venlasov XL Capsules.** 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 Venlasov XL Capsules').

- **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, tricyclic antidepressants, 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 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 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.

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 Venlasov XL Capsules 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)

Taking Venlasov XL Capsules with food and drink
Food
The capsules should be taken with food (How to take Venlasov XL Capsules).

Alcohol
Do not drink alcohol while being treated with Venlasov XL Capsules. 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 Venlasov XL Capsules only after discussing the potential benefits and risks to your unborn child with your doctor.

Make sure your midwife and/or doctor know you are on Venlasov XL Capsules. 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 Venlasov XL Capsules 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 Venlasov XL Capsules so they can advise you.

Venlafaxine 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 operate any tools or machines until you know how this medicine affects you.

3. How to take Venlasov XL Capsules

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

Recommended dose
The usual recommended starting dose for the treatment of depression, generalised anxiety disorder and social anxiety disorder is 75 mg taken once daily. 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.

You should swallow each capsule whole with a drink of water at approximately the same time each day, either in the morning or in the evening. Do not break open, crush or chew the capsules, or put them in water before swallowing.

Venlasov XL Capsules 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 Venlasov XL Capsules').

If you take more Venlasov XL Capsules than you should
If you realise you have taken more Venlasov XL Capsules than your doctor has recommended (or if someone else has taken some of your Venlasov XL Capsules), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.
Overdose can be life-threatening, especially with concomitant use of alcohol and/or certain medicines (see "Other medicines and Venlasov XL Capsules").
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 Venlasov XL Capsules
If you forget to take a dose, take it as soon as you remember unless it is nearly 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 the forgotten dose.
Do not take more than the daily amount of Venlasov XL Capsules that has been prescribed for you in one day.

If you stop taking Venlasov XL Capsules
Do not discontinue the treatment or reduce the dose without consulting your doctor, even if you feel better.

If your doctor thinks that you no longer need Venlasov XL Capsules, 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 Venlasov XL Capsules 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 may cause side effects, although not everybody gets them.

If any of the following happen, do not take more Venlasov XL Capsules. **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 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.

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
- 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 (muscle spasms or stiffness), seizures or fits
- Psychiatric problems, such as hyperactivity and feeling unusually overexcited
- Withdrawal effects (see the section ‘How to take Venlasov XL Capsules, If you stop taking Venlasov XL Capsules’).
- 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 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 Venlasov XL Capsules')
• Aggression
• Vertigo
• Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see section 2 'Pregnancy and breast-feeding'

Venlasov XL Capsules sometimes cause unwanted effects that you may not be aware of, such as increases in blood pressure or abnormal heartbeat; slight changes in blood levels of liver enzymes, sodium or cholesterol. More rarely, Venlasov XL Capsules 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 Venlasov XL Capsules 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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to Store Venlasov XL Capsules

Do not store above 25°C. Store in the original package in order to protect from moisture.
Keep out of the sight and reach of children
Do not use Venlasov XL Capsules 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 use Venlasov XL Capsules if you notice that the capsules are sticky or show any other visible signs of 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 to protect the environment.

6. Contents of the pack and other information

What Venlasov XL Capsules contain
The active substance is venlafaxine hydrochloride equivalent to 37.5 mg venlafaxine. Other ingredients are:
microcrystalline cellulose, copovidone, ethylcellulose, magnesium stearate, povidone, silica- colloidal anhydrous, talc.

The capsule shell for 37.5 mg capsules contains gelatin, titanium dioxide (E171), black iron oxide (E172), red iron oxide (E172), Iron oxide yellow (E172). The printing ink contains the following: shellac, propylene glycol, dehydrated alcohol, isopropyl alcohol, butyl alcohol, strong ammonia solution, red iron oxide (E172).

What Venlasov XL Capsules look like and contents of the pack
The 37.5 mg capsules are opaque, light gray and peach coloured prolonged-release hard capsules having red coloured, thick and thin radial circular bands on both ends of the capsules.

Venlasov XL 37.5 mg Capsules are available in blister packs of 7, 14, 28 or 56 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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