

## Package leaflet: Information for the user

**Venlafaxine SUN Pharma XL 37.5 mg prolonged-release tablets**  
**Venlafaxine SUN Pharma XL 75 mg prolonged-release tablets**  
**Venlafaxine SUN Pharma XL 150 mg prolonged-release tablets**

venlafaxine

### IMPORTANT THINGS YOU SHOULD KNOW ABOUT VENLAFAXINE SUN PHARMA XL

**Please read all of this leaflet before you start to take your medicine as it contains important information about Venlafaxine SUN Pharma XL**

- **Venlafaxine SUN Pharma 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)**
- **Venlafaxine SUN Pharma XL is not for use in children and adolescents – see in section 2 ‘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.**

- **Venlafaxine SUN Pharma 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 you start 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 themselves. 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 tablets 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 Venlafaxine SUN Pharma XL or change your dose without the advice of your doctor even if you feel better.** If you stop taking Venlafaxine SUN Pharma XL abruptly you may get withdrawal reactions – see in section 3 ‘If you stop taking Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma XL – see in section 2 ‘Before you take Venlafaxine SUN Pharma XL’**
- **Taking certain other medicines with Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma 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 in 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 Venlafaxine SUN Pharma XL is and what it is used for
2. What you need to know before you take Venlafaxine SUN Pharma XL
3. How to take Venlafaxine SUN Pharma XL
4. Possible side effects
5. How to store Venlafaxine SUN Pharma XL
6. Contents of the pack and other information

#### **1. What Venlafaxine SUN Pharma XL is and what it is used for**

Venlafaxine SUN Pharma 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.

Venlafaxine SUN Pharma XL is a medicine to treat adults with depression. Venlafaxine SUN Pharma XL is also used to treat 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 Venlafaxine SUN Pharma XL**

##### **Do not take Venlafaxine SUN Pharma 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 other medicines, including Venlafaxine SUN Pharma XL, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Venlafaxine SUN Pharma XL before you take any MAOI (see also “Other medicines and Venlafaxine SUN Pharma XL” and the information in the section about “Serotonin Syndrome”).

##### **Warnings and precautions**

If any of the following apply to you, please tell your doctor or pharmacist **before** taking Venlafaxine SUN Pharma XL

- if you use other medicines that taken together with Venlafaxine SUN Pharma XL could increase the risk of developing serotonin syndrome (see the section “Other medicines and Venlafaxine SUN Pharma 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 taking other medicines that may increase the risk of bleeding e.g., warfarin (used to prevent blood clots), or if you are pregnant (see 'Pregnancy')
- 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.

Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma 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 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 Venlafaxine SUN Pharma XL.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behaviour in adults (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 Venlafaxine SUN Pharma XL. Therefore, the dosage of your diabetes medicines may need to be adjusted.

### **Sexual problems**

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

### **Children and adolescents**

Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma XL. Also, the long-term safety concerning growth, maturation and cognitive and behavioural development of this medicine in this age group has not yet been demonstrated.

### **Other medicines and Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma 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 SUN Pharma XL treatment, particularly when taken with other medicines.  
Examples of these medicines include:
  - triptans (used to treat migraine)
  - other medicines used 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).

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 the 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 Venlafaxine SUN Pharma 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).

### **Venlafaxine SUN Pharma XL with food, drink and alcohol**

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

Do not drink alcohol while being treated with Venlafaxine SUN Pharma 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.

#### *Pregnancy*

Tell your doctor if you become pregnant, or if you are trying to become pregnant. You should use Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma 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, other symptoms your baby might have when it is born is not feeding properly, in addition to having trouble breathing. If your baby has these symptoms when it is born and you are concerned, contact your doctor and/or midwife who will be able to advise you.

If you take Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma XL so they can advise you.

#### *Breast-feeding*

Venlafaxine SUN Pharma 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.

### **Venlafaxine SUN Pharma XL contains lactose**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **Venlafaxine SUN Pharma XL contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

## **3. How to take Venlafaxine SUN Pharma XL**

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

### **Dosage**

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.

### **Method of administration**

Take this medicine at approximately the same time each day, either in the morning or in the evening. Tablets must be swallowed whole with fluid and not crushed, chewed or dissolved.

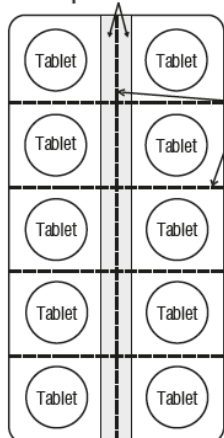
Venlafaxine SUN Pharma XL should be taken with food.

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

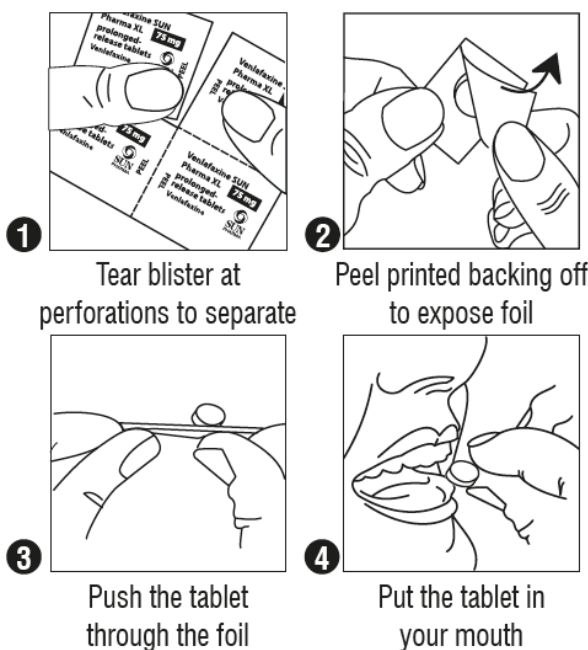
Do not stop taking this medicine without talking to your doctor (see the section “If you stop taking Venlafaxine SUN Pharma XL”).

### **PEEL INSTRUCTION**

Unsealed area for  
peel-off



Perforation



### **If you take more Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma XL**

Do not take a double dose to make up a forgotten tablet. If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual. Do not take more than the daily amount of Venlafaxine SUN Pharma XL that has been prescribed for you in one day.

#### **If you stop taking Venlafaxine SUN Pharma XL**

Do not stop taking this medicine or reduce the dose without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need Venlafaxine SUN Pharma XL, he/she may 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 Venlafaxine SUN Pharma XL. 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 you notice any of the following happen, do not take more Venlafaxine SUN Pharma 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 more 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: frequency 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, 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 information under 'If you stop taking Venlafaxine SUN Pharma XL ' in the section “How to take Venlafaxine SUN Pharma XL”)
- prolonged bleeding – if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop.

The coating does not dissolve completely and is passed out in your stools. Do not be concerned if you see small fragments in your stools after taking this medicine. Even though you may see these fragments, 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 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)
- 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, rash, 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: 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 Venlafaxine SUN Pharma XL”)
- aggression
- vertigo
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information.

Venlafaxine SUN Pharma 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, Venlafaxine SUN Pharma 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 Venlafaxine SUN Pharma 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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Venlafaxine SUN Pharma 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.

Blisters: Store in the original package in order to protect from moisture.

Tablet container: Keep the tablet container tightly closed in order to protect from moisture.

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 Venlafaxine SUN Pharma XL contains**

The active substance is venlafaxine.

Each prolonged-release tablet contains 37.5 mg, 75 mg or 150 mg venlafaxine (as venlafaxine hydrochloride).

The other ingredients are:

#### For 37.5 mg

##### Tablet core

Sustained release layer:

methyl hydroxypropyl cellulose,  
povidone K30,  
lactose monohydrate,  
methacrylic acid-ethyl acrylate copolymer (1:1),  
talc,  
magnesium stearate.

Openable layer:

microcrystalline cellulose silicified,  
crospovidone Type A,  
silica, colloidal anhydrous,  
sodium lauryl sulfate,  
allura red AC aluminium lake (E129),  
talc,  
magnesium stearate.

##### Coating

ethylcellulose aqueous dispersion,  
mannitol,  
povidone K30,  
dibutyl sebacate,  
triethyl citrate,  
polysorbate 20,  
opadry II 85F19250 clear, which consists of  
talc,  
macrogol 3350,  
polysorbate 80,

polyvinyl alcohol.

Printing ink (opacode-s-1-17823 black ink)

shellac,  
iron oxide black (E172),  
propylene glycol.

For 75 mg and 150 mg

Tablet core

Sustained release layer:  
methyl hydroxypropyl cellulose,  
povidone K30,  
lactose monohydrate,  
methacrylic acid-ethyl acrylate co-polymer (1:1),  
talc,  
magnesium stearate.

Openable layer:

microcrystalline cellulose silicified,  
crospovidone Type A,  
silica, colloidal anhydrous,  
sodium lauryl sulfate,  
allura red AC aluminium lake (E129),  
talc,  
magnesium stearate.

Coating

ethylcellulose aqueous dispersion,  
mannitol,  
povidone K30,  
dibutyl sebacate,  
triethyl citrate,  
polysorbate 20,  
talc  
opadry II 85F19250 clear, which consists of  
talc,  
macrogol 3350,  
polysorbate 80,  
polyvinyl alcohol.

Printing ink (opacode-s-1-17823 black ink)

shellac,  
iron oxide black (E172),  
propylene glycol.

**What Venlafaxine SUN Pharma XL looks like and contents of the pack**

**Venlafaxine SUN Pharma XL 37.5 mg:** This medicinal product is presented as a round, pink and white coloured biconvex, 5.9 mm in diameter bilayer coated prolonged-release tablet imprinted with “760” with black ink on one side and plain on the other side.

**Venlafaxine SUN Pharma XL 75 mg:** This medicinal product is presented as a round, pink and white coloured biconvex, 8.4 mm in diameter bilayer coated prolonged-release tablet imprinted with “759” with black ink on one side and plain on the other side.

**Venlafaxine SUN Pharma XL 150 mg:** This medicinal product is presented as an oval, pink and white coloured biconvex, 16.35 mm x 7.85 mm bilayer coated tablet imprinted with “758” with black ink on one side and plain on the other side.

Blister: Pack sizes 14, 15, 20, 28, 30, 50 or 100 prolonged-release tablets.

Tablet container: Pack sizes: 30 and 1000 (for dispensing only) prolonged-release tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

Sun Pharmaceutical Industries Europe B.V.  
Polarisavenue 87  
2132 JH Hoofddorp  
The Netherlands

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

Spain: Venlafaxina SUN 75 mg / 150 mg, comprimido de liberación prolongada  
The Netherlands: Venlafaxine SUN 37,5 mg / 75 mg / 150 mg, tablet met verlengde afgifte  
United Kingdom (Northern Ireland): Venlafaxine SUN Pharma XL 37.5 mg / 75 mg / 150 mg, prolonged-release tablets

**This leaflet was last revised in 04/2025.**