

PACKAGE LEAFLET: INFORMATION FOR THE USER

<Venlafaxine> 25 mg Tablets
<Venlafaxine> 37.5 mg Tablets
<Venlafaxine> 50 mg Tablets
<Venlafaxine> 75 mg Tablets
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 of the 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> is and what it is used for
2. What you need to know before you take <Venlafaxine>
3. How to take <Venlafaxine>
4. Possible side effects
5. How to store <Venlafaxine>
6. Contents of the pack and other information

1. WHAT <VENLAFAXINE> IS AND WHAT IT IS USED FOR

<Venlafaxine> 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> is a treatment for adults with depression. Treating depression 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>

Do not take <Venlafaxine>

- 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, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking <Venlafaxine> before you take any irreversible MAOI (see also the section "Other medicines and <Venlafaxine>" including bullet point(s) on serotonin syndrome).

Warnings and precautions

Talk to your doctor or pharmacist before taking <Venlafaxine>

- If you use other medicines that taken concomitantly with <Venlafaxine> could increase the risk of developing serotonin syndrome (see the section "Other medicines and <Venlafaxine>").

- 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)
- If your cholesterol levels get higher.
- 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.
- If you use weight loss preparations; it is not recommended to use them together with <Venlafaxine>.

<Venlafaxine> 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. Tell the doctor that you are taking <Venlafaxine> if you have to provide a urine sample.

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 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 <Venlafaxine>. Therefore, the dosage of your diabetes medicines may need to be adjusted.

Children and adolescents

<Venlafaxine> 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 <Venlafaxine> for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed

<Venlafaxine> 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>. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of <Venlafaxine> in this age group has not yet been demonstrated.

Other medicines and <Venlafaxine>

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

Your doctor should decide whether you can take <Venlafaxine> 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>. Tell your doctor if you have taken these medicines within the last 14 days (MAOIs: see the section "Do not take <Venlafaxine>").

- Serotonin syndrome:

Serotonin syndrome, a potentially life-threatening condition (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)
- 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)
- Methylene blue, a reversible MAOI (used to treat a condition known as methemoglobinaemia)
- Medicines containing sibutramine (used for weight loss)
- Medicines containing tramadol, methadone, dextromethorphan, fentanyl, tapentadol, pethidine, or pentazocine (a pain-killer)
- 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. Get medical care right away if you think serotonin syndrome is happening to you.

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).

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 infection)
- Antihistamines (used to treat allergy)

The following medicines may also interact with <Venlafaxine> 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)
- Imipramine (to treat depression)
- Diazepam (to treat anxiety or sleeping problems)
- Indinavir (to treat HIV/AIDS)

Tell your doctor if you are taking oral contraceptives.

<Venlafaxine> with food drink and alcohol

<Venlafaxine> should be taken with food (see section 3 “How to take <Venlafaxine>”).

You should avoid alcohol while you are taking <Venlafaxine>.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.. You should use <Venlafaxine> 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>. 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.

<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 <Venlafaxine>.

Driving and using machines

Do not drive or use any tools or machines until you know how <Venlafaxine> affects you

<Venlafaxine> 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.

3. HOW TO TAKE <VENLAFAXINE>

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 is 75 mg per day in divided doses, two or three times a 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.

Take <Venlafaxine> at approximately the same time each day, in the morning and in the evening.

<Venlafaxine> should be taken with food.

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

Do not stop taking <Venlafaxine> without talking to your doctor (see the section “If you stop taking <Venlafaxine>”).

If you take more <Venlafaxine> than you should

Call your doctor or pharmacist immediately if you take more than the amount of <Venlafaxine> prescribed by your doctor.

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

If you forget to take <Venlafaxine>

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> that has been prescribed for you in one day.

If you stop taking <Venlafaxine>

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 <Venlafaxine>, he/she may ask you to reduce your dose slowly, before stopping treatment altogether. Side effects are known to occur when people stop using <Venlafaxine>, especially when <Venlafaxine> 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 <Venlafaxine> 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 <Venlafaxine>. 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 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).

- Yellow skin or eyes, itchiness or dark urine, which may be symptoms of inflammation of the liver (hepatitis)
- Thoughts of harming or killing yourself - cases of suicidal ideation and suicidal behaviours have been reported during venlafaxine therapy or early after treatment discontinuation (see section 2, Do not take <Venlafaxine>)
- 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 that may present in e.g. high fever or sore throat

Serious side effects

If you notice any signs of the following, you may need urgent medical attention:

- Coughing, wheezing, shortness of breath and a high temperature
- Black (tarry) stools or blood in stools
- Heart problems, such as fast or irregular heart rate, increased blood pressure
- Eye problems, such as blurred vision, dilated pupils
- Nerve problems, such as 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 <VENLAFAXINE>, If you stop taking <Venlafaxine>”)
- Prolonged bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop.

Other reported side effects

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

Digestive disorders: nausea; dry mouth

Nervous system disorders: headache

Skin disorders: sweating (including night sweats)

Common (may affect up to 1 in 10 people)

Breathing disorders: yawning

Digestive disorders: appetite decreased; constipation; vomiting; diarrhoea

Heart or circulation disorders: increase in blood pressure; flushing; palpitations

General: weakness (asthenia); fatigue; chills

Metabolism/nutritional disorders: increased cholesterol

Nervous system disorders: abnormal dreams; decreased libido; increased muscle tonus; insomnia; nervousness; drowsiness; tremor; feeling separated (or detached) from yourself and reality

Reproductive and sexual disorders: abnormal ejaculation/orgasm (males); lack of orgasm; erectile dysfunction (impotence); menstrual irregularities such as increased bleeding or increased irregular bleeding

Sight and hearing disorders: 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)

Urinary system disorder: difficulties passing urine; increased frequency in urination

Uncommon (may affect up to 1 in 100 people)

Blood disorders: bruising; vomiting blood

Digestive disorder: grinding of the teeth *Heart or circulation disorders:* feeling dizzy (particularly when standing up too quickly), fainting, fast heartbeat

General: sensitivity to sunlight, 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

Breathing disorders: shortness of breath

Metabolism/nutritional disorders: weight gain, weight loss

Nervous system disorders: lack of feeling or emotion; hallucinations; feeling separated (or detached) from reality; involuntary movement of the muscles; agitation; impaired coordination and balance; a sensation of restlessness or an inability to sit or stand still, feeling over-excited

Reproductive and sexual disorders: abnormal orgasm (females)

Skin disorders: rash; abnormal hair loss

Sight and hearing disorders: altered taste sensation

Urinary system disorders: inability to pass urine

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

Nervous system disorders: seizures or fits, over activity, racing thoughts and decreased need for sleep (mania).

Urinary system disorders: inability to control urination

Frequency Not known (frequency cannot be estimated from the available data)

Digestive disorders: severe abdominal or back pains (which could indicate a serious problem in the gut, liver or pancreas)

General: swollen face or tongue, shortness of breath or difficulty breathing, often with skin rashes (this may be a serious allergic reaction)

Heart or circulation disorders: decrease in blood pressure; abnormal, rapid or irregular heart beat, 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)

Metabolism/nutritional disorders: slight changes in blood levels of liver enzymes; decrease in blood sodium levels; excessive water intake (known as SIADH); abnormal breast milk production

Muscle disorders: unexplained muscle pain, tenderness or weakness (rhabdomyolysis)

Nervous system disorders: euphoric feelings, drowsiness, sustained rapid eye movement, clumsiness, restlessness, feeling of being drunk, sweating or rigid muscles, which are symptoms of serotonergic syndrome; disorientation often accompanied by hallucination (delirium); stiffness, spasms and involuntary movements of the muscles; vertigo; aggression

Skin disorders: skin rash, which may lead to severe blistering and peeling of the skin; itching; mild rash

Sight and hearing disorders: severe eye pain and decreased or blurred vision

<Venlafaxine> 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> 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> 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 the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.*

5. HOW TO STORE <VENLAFAXINE>

Keep 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 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> contains

- The active substance is <Venlafaxine>. Each tablet contains 25 mg, 37.5 mg, 50 mg, 75 mg of <Venlafaxine> (as hydrochloride).
- The other ingredients are lactose monohydrate, lactose spray-dried, sodium starch glycolate (type A), colloidal silica anhydrous, magnesium stearate, yellow iron oxide (E172) and red iron oxide (E172).

What <Venlafaxine> looks like and contents of the pack

- 25 mg tablets: Mottled peach, round, flat beveled tablet, scored on one side and debossed "9" on one side of the score and "3" on the other side, debossed "199" on the opposite side of the tablet. The tablet can be divided into equal halves and is available in pack sizes of 30 and 60 tablets. A hospital pack size of 50 tablets is also available.
- 37.5 mg tablets: Mottled peach, round, flat beveled tablet, scored on one side and debossed "9" on one side of the score and "3" on the other side, debossed "7380" on the opposite side of the tablet. The score line is only to facilitate breaking for ease of swallowing and not to divide into

equal doses. The tablets are available in pack sizes of 10, 20, 28, 30, 50, 56, 60 and 100 tablets. A hospital pack size of 50 tablets is also available.

- 50 mg tablets: Mottled peach, round, flat beveled tablet, scored on one side and debossed "9" on one side of the score and "3" on the other side, debossed with "7381" on the opposite side of the tablet. The tablet can be divided into equal halves and is available in pack sizes of 28, 30, 42, 56, 60 and 100 tablets. A hospital pack size of 50 tablets is also available.
- 75 mg tablets: Mottled peach, round, flat beveled tablet, scored on one side and debossed "9" on one side of the score and "3" on the other side, debossed with "7382" on the opposite side of the tablet. The tablet can be divided into equal halves and is available in pack sizes of 20, 28, 30, 50, 56, 60 and 100 tablets. Hospital pack sizes of 50 and 500 tablets are also available.
- Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

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

DE: Venlafaxin Teva 37,5 mg Tabletten

FR: <Venlafaxine> Teva 50 mg, comprimé

IE: <Venlafaxine> Teva 37.5 & 75 mg tablets

UK: <Venlafaxine> 25, 37.5, 50 & 75 mg Tablets

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APPROVALS

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Nitin Kudale	Regulatory Affairs Approval	22-Jul-2015 11:09:55 AM