

PACKAGE LEAFLET: INFORMATION FOR THE USER

Velafax

75 mg Tablets

VENLAFAXINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Velafax is and what it is used for
2. What you need to know before you take Velafax
3. How to take Velafax
4. Possible side effects
5. How to store Velafax

1. WHAT Velafax IS AND WHAT IT IS USED FOR

The name of your medicine is Velafax 75 mg Tablets (referred to as Velafax throughout this leaflet).

Velafax 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. 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.

Velafax 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 Velafax

Do not take Velafax

- If you are allergic to venlafaxine or any of the other ingredients of Velafax.
- 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 Velafax, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Velafax before you take any MAOI (see also the section entitled "Other medicines and Velafax" and the information in that section about "Serotonin syndrome").

Warnings and precautions

If any of the following apply to you, please tell your doctor before taking Velafax:

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

Velafax 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.

Thoughts of suicide and worsening of your depression or anxiety

If you are depressed and/or anxious, you can sometimes have thoughts of harming or killing yourself. These may be increased when you first start taking antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing yourself or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or anxious, 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 Velafax. Therefore, the dosage of your diabetes medicines may need to be adjusted.

Children and adolescents

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

Other medicines and Velafax

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.

Your doctor should decide whether you can take Velafax with other medicines, such as:

- Monoamine oxidase inhibitors which are used to treat depression or Parkinson's disease must not be taken with Velafax. 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 Velafax").
- Products associated with serotonin syndrome:

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 (a pain-killer), 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 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 Velafax 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)
- Oral contraceptives

Taking Velafax with food and drink

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

You should avoid alcohol while you are taking Velafax.

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 Velafax only after discussing the potential benefits and the potential risks to your unborn child with your doctor.

Make sure your midwife and/or doctor know you are on Velafax. 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 Velafax 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.

Velafax 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 Velafax.

Driving and operating machinery

Venlafaxine can cause impaired judgement, thinking, and movement and coordination as well as problems with vision. If you are affected by any of these you should not drive, operate machinery or take part in any activities where such effects could put you or others at risk.

Important information about some of the ingredients of Velafax

This product 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 VELAFAX

Always take Velafax exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual recommended starting dose is 75 mg per day in divided doses. 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 Velafax at approximately the same time each day, in the morning and in the evening.

Velafax should be taken with food.

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

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

If you take more Velafax than you should

Call your doctor or pharmacist immediately if you take more than the amount of Velafax 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 Velafax

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 Velafax that has been prescribed for you in one day.

If you stop taking Velafax

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 Velafax, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using Velafax, especially when Velafax 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 Velafax 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Velafax can cause side effects, although not everybody gets them.

If any of the following happen, do not take more Velafax. 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

Frequency not known (cannot be estimated from the available data)

- Chest tightness, wheezing, trouble swallowing or breathing
- Severe rash, itching, or hives (elevated patches of red or pale skin that often itch)
- Signs and symptoms of serotonin syndrome which may include restlessness, hallucinations, loss of coordination, fast 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).
- Signs of infection, such as high temperature, chills, shivering, headaches, sweating, flu-like symptoms. This may be the result of a blood disorder which leads to an increased risk of infection.
- Severe rash, which may lead to severe blistering and peeling of the skin.
- Unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.

Other side effects that you should tell your doctor about include (The frequency of these side effects are included in the list "Other side effects that may occur" below):

- Coughing, wheezing, shortness of breath and 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 euphoria (feeling unusually overexcited)

- Withdrawal effects (see the section “How to take Velafax, if you stop taking Velafax”)
- 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
- 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 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)
- 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
- 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 (cannot be estimated from the available data)

- prolonged bleeding, which may be a sign of reduced number of platelets in your blood, leading to an increased risk of bruising or bleeding
- 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, What you need to know before you take Velafax)
- disorientation and confusion often accompanied by hallucination (delirium); aggression
- 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 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)
- 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
- itching; mild rash
- abnormal breast milk production

Velafax 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, Velafax 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 Velafax for a long time.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

5. HOW TO STORE Velafax

Keep out of the reach and sight of children.

Do not use Velafax after the expiry date, which is stated on the packaging.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

This leaflet was last revised in January 2016