

PACKAGE LEAFLET: Information for the patient

FALAXIN

Tablets – 37.5 mg

(Venlafaxine hydrochloride)

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 Falaxin is and what it is used for
2. What you need to know before you take Falaxin
3. How to take Falaxin
4. Possible side effects
5. How to store Falaxin
6. Contents of the pack and other information

1. WHAT FALAXIN IS AND WHAT IT IS USED FOR

Falaxin 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.

Falaxin 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 FALAXIN

Do not take Falaxin:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Falaxin. If any of the following applies to you, please tell your doctor **before** taking Falaxin:

- if you use other medicines that when taken together with Falaxin could increase the risk of developing serotonin syndrome (see section "Other medicines and Falaxin");
- if you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye);
- if you have a history of high blood pressure;
- if you have a history of heart problems;
- if you have a history of fits (seizures);
- if you have a history of low sodium levels in your blood (hyponatraemia);
- if you have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders), or if you are 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 and breastfeeding');
- if you have a history, 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.

Falaxin may cause a sensation of restlessness or 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 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 are first starting antidepressants, since all these medicines 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 aged less than 25 years 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 caries. Therefore, you should take special care in your dental hygiene.

Diabetes

Your blood glucose levels may be altered due to Falaxin and your diabetes medicines may need to be adjusted.

Sexual problems

Medicines like Falaxin (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

Falaxin should normally not be used for children and adolescents under 18 years. Also, you should know that patients under the age of 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 Falaxin for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Falaxin for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 take Falaxin. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of this medicine in this age group, have not yet been demonstrated.

Other medicines and Falaxin

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

Your doctor should decide whether you can take Falaxin 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 Falaxin**. Tell your doctor if you have taken these medicines within the last 14 days (MAOIs: see section 2. "What you need to know before you take Falaxin").

Serotonin syndrome

A potentially life threatening condition or Neuroleptic Malignant Syndrome (NMS)-like reactions (see section 4. "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 SNRIs, SSRIs, tricyclics, or medicines containing lithium;
- 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 (a pain-killer);

- 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 feeling 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 emergency 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 such as:

- 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 Falaxin and should be used with caution. It is especially important to mention to your doctor or pharmacist if you are taking medicines containing:

- ketoconazole, itraconazole, voriconazole, posaconazole (antifungal medicines);
- haloperidol or risperidone (to treat psychiatric conditions);
- metoprolol (a beta blocker to treat high blood pressure and heart problems);
- atazanavir, nelfinavir, ritonavir, saquinavir, indinavir (antiviral medicines).

Falaxin with alcohol

You should avoid alcohol while you are taking Falaxin.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 Falaxin only after discussing the potential benefits and the potential risks to your unborn child with your doctor.

If you take Falaxin 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 Falaxin so they can advise you. 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 doctor immediately.

If you are taking this medicine during pregnancy, other symptoms your baby might have when he/she is born is not feeding properly in addition to having trouble breathing. If your baby has these symptoms when he/she is born and you are concerned, contact your doctor who will be able to advise you.

Falaxin 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 breastfeeding or stop the therapy with this medicine.

Driving and using machines

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

3. HOW TO TAKE FALAXIN

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

The usual recommended starting dose for treatment of depression is 75 mg per day in 2 to 3 divided doses. The dose can be raised by your doctor gradually, and if needed, even up to a maximum dose of 375 mg daily.

Take Falaxin at approximately the same time each day, either in the morning or in the evening. The tablets must be swallowed with fluid. Falaxin should be taken with food.

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

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

If you take more Falaxin than you should

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

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

If you forget to take Falaxin

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

If you stop taking Falaxin

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 Falaxin, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using Falaxin, especially when Falaxin 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, vomiting, 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 Falaxin 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 happens, do not take more Falaxin. **Tell your doctor immediately, or go to the emergency 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;
- severe rash, itching, or hives (elevated patches of red or pale skin that often itch);
- signs and symptoms of serotonin syndrome which may include: restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting; in its most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS); signs and symptoms of NMS may include a combination of fever, fast heartbeat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test);
- 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.

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 Falaxin');
- signs and symptoms of a condition called "stress cardiomyopathy" that may include: chest pain, shortness of breath, dizziness, fainting, irregular heartbeat.

Other side effects that you should tell your doctor about include (their frequency is defined below):

- coughing, wheezing, shortness of breath and high temperature;
- black (tarry) stools or blood in stools;
- yellow skin or eyes, itchiness or dark urine, which may be symptoms of inflammation of the liver (hepatitis);
- heart problems, such as fast or irregular heart rate, increased blood pressure;
- eye problems, such as blurred vision, dilated pupils;
- nerve problems, such as dizziness, pins and needles, movement disorder, seizures or fits;
- psychiatric problems, such as hyperactivity and euphoria (feeling unusually overexcited);
- withdrawal effects (see section 3. "How to take Falaxin" and "If you stop taking Falaxin").

Other side effects

Very common: may affect more than 1 in 10 people

- dizziness, headache, drowsiness;
- nausea, dry mouth, constipation;
- insomnia;
- 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, feeling nervous or anxious, abnormal dreams;
- paraesthesia;
- tremor, a sensation of restlessness or an ability to sit or stand still, 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 heart beat, palpitations;
- increase in blood pressure, flushing;
- shortness of breath, yawning;
- vomiting, diarrhoea;
- 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, increased cholesterol;
- weight gain; weight loss.

Uncommon: may affect up to 1 in 100 people

- hallucinations, feeling separated (or detached) from reality, abnormal orgasm (females), lack of feeling or emotion, feeling over-excited, grinding of the teeth;
- over activity, racing thoughts and decreased need for sleep (mania);
- 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;
- general swelling of the skin especially the face, mouth, tongue, throat area or hands and feet, 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 hallucinations (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;
- 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).

Not known: frequency cannot be estimated from the available data

- aggression;
- vertigo;
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy and breastfeeding' for more information.

Falaxin 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 of liver enzymes, sodium or cholesterol. More rarely, Falaxin 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 Falaxin for a long time. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE FALAXIN

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 package!

Store below 25°C.

Keep in the original package to protect it from humidity!

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Falaxin contains

The active substance is venlafaxine hydrochloride.

Each tablet contains venlafaxine hydrochloride equivalent to 37.5 mg venlafaxine.

The excipients are: microcrystalline cellulose, pregelatinized starch, iron oxide yellow, povidone, sodium starch glycolate, magnesium stearate.

Contents of the pack

Box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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