

Package leaflet: Information for the user

Venlafaxine Fair-Med 37,5 mg capsules met verlengde afgifte, hard
Venlafaxine Fair-Med 75 mg capsules met verlengde afgifte, hard
Venlafaxine Fair-Med 150 mg capsules met verlengde afgifte, hard

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

1. What <Product Name> is and what it is used for

<Product name> 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.

<Product name> is a treatment for adults with depression. <Product name> is also a treatment for adults with the following anxiety disorders: generalised anxiety disorder, social anxiety disorder (fear or avoidance of social situations) and panic disorder (panic attacks). Treating depression or anxiety disorders properly is important to help you get better. If it is not treated, your condition may not go away and may become more serious and more difficult to treat.

2. What you need to know before you take <Product name>

Do not take <Product name>

- 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 <Product name>, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking <Product name> before you take any MAOI (see also the section "Taking other medicines").

Take special care with <Product name>

- if you use other medicines that taken concomitantly with <Product name> could increase the risk of developing serotonin syndrome (see the section “Taking other medicines”)
- 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 pregnant (see ‘Pregnancy and breast-feeding’) or if you are taking other medicines that may increase the risk of bleeding
- 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.

<Product name> may cause a sensation of restlessness or an inability to sit or stand still. You should tell your doctor if this happens to you.

If any of these conditions apply to you, please talk with your doctor before taking <Product name>.

Medicines like <Product name> (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Do not drink alcohol while being treated with <product name> 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.

You may be more likely to think like this:

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

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

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Dry mouth

Dry mouth is reported in 10% of patients treated with venlafaxine. This may increase the risk of caries. Therefore, you should take special care in your dental hygiene.

Children and adolescents

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

Other medicines and <Product name>

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

Your doctor should decide whether you can take <Product name> 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 "Before you take venlafaxine").

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)
- 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)
- Products containing St. John's wort (also called *Hypericum perforatum*, a natural or herbal remedy used to treat mild depression)
- Products containing tryptophan (used for problems such as sleep and depression).
- Antipsychotics (used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, unclear reasoning and becoming withdrawn)

Signs and symptoms of serotonin syndrome may include a combination of the following: restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea, vomiting. Get medical care right away if you think serotonin syndrome is happening to you.

The following medicines may also interact with <Product name> 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).

<Product name> with food and drink

<Product name> should be taken with food (see section 3). Do not drink alcohol while being treated with [product name]. 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

Tell your doctor if you become pregnant, or you are trying to become pregnant. You should use <Product name> 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 <Product name>. 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 take <product name> 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 <product name> so they can advise you.

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.

<Product name> 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 <Product name>.

Driving and using machines

Do not drive or use any tools or machines until you know how <Product name> affects you.

3. How to take <Product name>

Always take <Product name> 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 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.

Take <Product name> at approximately the same time each day, either in the morning or in the evening. Capsules must be swallowed whole with fluid and not opened, crushed, chewed or dissolved.

<Product name> should be taken with food.

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

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

If you take more <Product name> than you should

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

Overdose can be life-threatening, especially with concomitant use of alcohol and/or certain medicines (see “Other medicines and <product name>”).

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 <Product name>

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 <Product name> that has been prescribed for you in one day.

If you stop taking <Product name>

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 <Product name>, he/she may ask you to reduce your dose slowly before stopping treatment altogether. Side effects are known to occur when people stop using <Product name>, especially when <Product name> 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 <Product name> 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, this medicine can cause side effects, although not everybody gets them.

Allergic reactions

If any of the following happen, do not take more <Product name>. 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 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).

Other side effects that you should tell your doctor about include:

- Coughing, wheezing, shortness of breath and a high temperature

- Black (tarry) stools or blood in stools
- Yellow skin or eyes, itchininess 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 the section “HOW TO TAKE <Product name, if you stop taking <Product name>”).

Do not be concerned if you see small white granules or balls in your stools after taking <Product name>. Inside <Product name> capsules are spheroids or small white balls that contain the venlafaxine active ingredient. These spheroids are released from the capsule into your gastrointestinal tract. As the spheroids travel the length of your gastrointestinal tract, venlafaxine is slowly released.

The spheroid “shell” remains undissolved and is eliminated in your stools. Therefore, even though you may see spheroids in your stools, your dose of venlafaxine has been absorbed.

Other reported side effects

Very common (affects more than 1 in 10 users)

- Headache; dry mouth; sweating (including night sweats)
- Nausea

Common (affects 1 to 10 users in 100)

- Weight loss; appetite decreased; constipation; vomiting; increased cholesterol
- Feeling separated (or detached) from yourself and reality; nervousness; confusion; abnormal dreams; insomnia
- Tremor; increased muscle tonus
- Pins and needles
- Increase in blood pressure; flushing, palpitations
- Increased frequency in urination; difficulties passing urine
- Decreased libido; abnormal ejaculation/orgasm (males); lack of orgasm; erectile dysfunction (impotence)
- Menstrual irregularities such as increased bleeding or increased irregular bleeding
- Weakness (asthenia); dizziness; sedation, chills
- Blurred vision
- Yawning

Uncommon (affects 1 to 10 users in 1,000)

- Bruising; black tarry stools (faeces) or blood in stools, which can be a sign of internal bleeding
- Grinding of the teeth; involuntary movement of the muscles
- Hallucinations
- 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
- Sensitivity to sunlight; abnormal hair loss; rash

- Impaired coordination and balance; feeling dizzy (particularly when standing up too quickly), fainting, fast heartbeat
- Weight gain; diarrhoea
- Altered taste sensation
- Lack of feeling or emotion; agitation
- Ringing in the ears (tinnitus)
- Inability to pass urine;
- Abnormal orgasm (females)

Rare (affects 1 to 10 users in 10,000)

A sensation of restlessness or an inability to sit or stand still; seizures or fits; feeling over-excited or euphoric.

- Inability to control urination

Frequency not known

- 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; slight changes in blood levels of liver enzymes; decrease in blood sodium levels;
- Itchiness, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis)
- Excessive water intake (known as SIADH)
- Abnormal breast milk production
- A high temperature with rigid muscles, confusion or agitation, and sweating, or if you experience jerky muscle movements which you can't control, these may be symptoms of serious conditions known as neuroleptic malignant syndrome
- Euphoric feelings, drowsiness, sustained rapid eye movement, clumsiness, restlessness, feeling of being drunk, sweating or rigid muscles, which are symptoms of serotonergic syndrome
- Disorientation and confusion often accompanied by hallucination (delirium)
- Stiffness, spasms and involuntary movements of the muscles
- Thoughts of harming or killing yourself
- Severe eye pain and decreased or blurred vision
- Decrease in blood pressure; abnormal, rapid or irregular heartbeat, which could lead to fainting
- 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)
- Skin rash, which may lead to severe blistering and peeling of the skin; itching; mild rash
- Unexplained muscle pain, tenderness or weakness (rhabdomyolysis)
- Swollen face or tongue, shortness of breath or difficulty breathing, often with skin rashes (this may be a serious allergic reaction)
- Confusion
- Vertigo
- Aggression
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy and breast-feeding' in section 2 for more information

<Product name> sometimes causes unwanted effects that you may not be aware of, such as increases in blood pressure or abnormal heartbeat; slight changes in blood levels or liver enzymes, sodium or cholesterol. More rarely, <Product name> 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 <Product name> 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 <Product name>

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 packaging after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

If your doctor decides to stop treatment, return any leftover capsules to your pharmacist. Only keep them if your doctor tells you to.

REMEMBER this medicine is only for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their signs of illness are the same as yours.

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 <Product name> contains

The active substance is Venlafaxine.

<Product Name> 37.5mg capsules contain venlafaxine hydrochloride, equivalent to 37.5mg of venlafaxine .

<Product Name> 75mg capsules contain venlafaxine hydrochloride, equivalent to 75mg of venlafaxine .

<Product Name> 150mg capsules contain venlafaxine hydrochloride, equivalent to 150mg of venlafaxine .

The other ingredients are:

Core:

Microcrystalline cellulose (Avicel PH 102)

Povidone (Plasdone K-90 D)

Hydroxypropyl methylcellulose

Talc

Silica, Colloidal Anhydrous

Magnesium stearate

Film Coating:

Ethyl Cellulose (Ethocel 7 CP STD Premium FP)
Copovidone (Plasdone S-630)

Capsule:

37.5 mg
Black Iron Oxide (E172)
Red Iron Oxide (E172)
Yellow Iron Oxide (E172)
Titanium Dioxide (E171)
Gelatin
Shellac
Propylene Glycol
Strong Ammonia Solution

75 mg
Black Iron Oxide (E172)
Red Iron Oxide(E172)
Titanium Dioxide (E171)
Gelatin
Shellac
Propylene Glycol
Strong Ammonia Solution

150 mg
Brilliant Blue FCF (E133)
Allura Red AC (E129)
Sunset Yellow FCF (E110)
Titanium Dioxide (E171)
Gelatin
Shellac
Povidone
Propylene Glycol
Sodium Hydroxide

What <Product Name> looks like and contents of the pack

Prolonged-release capsule, hard

<Product Name> 37.5mg: light grey opaque / peach opaque, size “3” hard gelatin capsules having thick and thin radial circular band on the body in red ink and thick and thin radial circular band on the cap in red ink. The capsule is filled with 3 white to off-white, round biconvex, film-coated mini tablets of 12.5mg each.

<Product Name> 75mg: peach opaque / peach opaque, size “1” hard gelatin capsules having thick and thin radial circular band on the body in red ink and thick and thin radial circular band on the cap in red ink. The capsule is filled with 6 white to off-white, round biconvex, film-coated mini tablets of 12.5mg each.

<Product Name> 150mg: dark orange / dark orange opaque, size “0” hard gelatin capsules having thick and thin radial circular band on the body in white ink and thick and thin radial circular band on the cap in white ink. The capsule is filled with 12 white to off-white, round biconvex, film-coated mini tablets of 12.5mg each.

Blister pack of PVC/ACLAR film or PVC/PVdC film and Aluminium lidding foil.

Pack-sizes

37.5mg: 7, 10, 14, 20, 28, 30, 50, 90, 100, 500 capsules

75mg: 10, 14, 20, 28, 30, 50, 56, 60, 90, 100, 500 capsules

150mg: 14, 20, 28, 30, 50, 60, 90, 100, 250, 500 capsules

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

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Duitsland

In het register ingeschreven onder:

Venlafaxine Fair-Med 37,5 mg capsules met verlengde afgifte, hard 108165

Venlafaxine Fair-Med 75 mg capsules met verlengde afgifte, hard 108166

Venlafaxine Fair-Med 150 mg capsules met verlengde afgifte, hard 108167

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

NL: Venlafaxine Fair-Med 37,5/75/150mg capsules met verlengde afgifte, hard

DE: Venlafaxin Fair-Med 37.5mg, 75mg, 150mg Hartkapseln, retardiert

Deze bijsluiter is voor het laatst goedgekeurd in maart 2023.