

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ENLAFAX® XR

Venlafaxine (as hydrochloride) 37.5 mg, 75 mg & 150 mg modified release capsules



What is in this leaflet

Please read this leaflet carefully before you start taking Enlafax XR.

This leaflet answers some common questions about Enlafax XR.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Enlafax XR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Enlafax XR is used for

Enlafax XR is used in the treatment and prevention of relapse of depression. It is also used in the treatment of panic attacks and anxiety, including avoidance or fear of social situations.

Depression can affect your whole body and may cause emotional and physical symptoms such as feeling low in spirit, being unable to enjoy life, poor appetite or overeating, disturbed sleep, loss of sex drive, lack of energy and feeling guilty over nothing.

Excessive anxiety is a condition in which you feel constantly and

uncontrollably worried and distressed. It may also make you feel irritable, and cause difficulty in thinking and sleeping. Other common symptoms associated with anxiety may include a dry mouth, a lump in the throat, cold clammy hands, diarrhoea and nausea.

Depression and anxiety are treatable illnesses. Anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

Enlafax XR contains the active ingredient venlafaxine hydrochloride. It belongs to a group of medicines called serotonin noradrenaline reuptake inhibitors (SNRIs).

Serotonin and noradrenaline are chemical messengers that allow certain nerves in the brain to work. Enlafax XR capsules increase the level of these two messengers.

Enlafax XR is not addictive.

This medicine is available only with a doctor's prescription.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take Enlafax XR

When you must not take it

Do not take Enlafax XR if you have an allergy to:

- any medicine containing venlafaxine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Enlafax XR if you are taking other medications for depression known as monoamine oxidase inhibitors, even if you have stopped taking them now, but have taken them within the last 14 days.

Do not give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness in patients younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a history of fits (seizures or convulsions)
- a personal history or family history of bipolar disorder
- a history of aggression
- a history of restlessness or difficulty sitting still
- diabetes
- blood pressure problems
- glaucoma (increased pressure in the eye)
- a tendency to bleed more than normal or you are taking medicines to prevent blood clots
- raised cholesterol levels or you are taking medicines to lower cholesterol
- problems with your kidneys or liver
- problems with your heart, especially conditions causing irregular heartbeats.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Enlafax XR.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Enlafax XR may interfere with each other. These include:

- medications for depression known as monoamine oxidase inhibitors (such as moclobemide, linezolid, phenelzine and tranylcypromine), even if you have stopped taking them now, but have taken them within the last 14 days. Your doctor or pharmacist can tell

you what to do if you are taking any of these medicines

- any other medications for depression, anxiety, obsessive compulsive disorder or premenstrual dysphoric disorder, including St John's wort
- medicines for treating mental disorders such as haloperidol, risperidone, lithium or clozapine
- tramadol, fentanyl, dextromethorphan, tapentadol, pentazocine, pethidine and methadone used to treat strong pain
- medicines used to treat Attention Deficit Hyperactivity Disorder (ADHD) such as dexamphetamine and lisdexamphetamine
- cimetidine for reflux and stomach ulcers
- triptans used to treat migraine
- amiodarone or quinidine used to treat irregular heartbeats.

These medicines may be affected by Enlafax XR or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor may do some tests such as an electrocardiogram (ECG) or blood tests if you are taking these medicines whilst taking Enlafax XR.

- metoprolol for high blood pressure or angina
- medicines used to prevent blood clotting such as anticoagulants and platelet inhibitors
- indinavir for viral infections
- antibiotics such as erythromycin and linezolid for bacterial infections
- ketoconazole or fluconazole for fungal infections.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Enlafax XR

Do not divide, crush, chew or dissolve the capsules.

Taking divided, chewed or crushed Enlafax-XR capsules, in theory, could lead to the rapid release and absorption of venlafaxine.

Do not be concerned if you see inert components of the capsule in your stools after taking Enlafax XR.

The capsules are designed to release the medicine (venlafaxine) slowly as they travel through your stomach and intestines. Some parts of the capsule components do not dissolve and are passed out in your stools. Therefore, even though you may see capsule components in your stools, your dose of medicine has been absorbed.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Depression and Anxiety

The usual starting dose is 75 mg taken once daily. If necessary, after two weeks, your doctor may increase your dose to 150 mg taken once daily.

Panic attacks

The usual starting dose is 37.5 mg taken once daily for the first 4 to 7 days, then increased to 75 mg taken once daily.

Do not change dose unless your doctor tells you to.

If you have kidney or liver problems, you may need a lower dose of Enlafax XR.

If you have heart problems and your doctor wishes to increase your

dose of Enlafax XR, your doctor may first do some blood tests or heart tests such as an electrocardiogram (ECG).

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take your medicine once daily with food, at approximately the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Avoid drinking alcohol while you are taking Enlafax XR.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Although you may begin to feel better after two weeks, it may take several weeks before you feel much better. It is important to give Enlafax XR time to work.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Enlafax XR. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, vomiting, changes to heart rate/rhythm, seizures, breathing difficulties, unconsciousness and dilated pupils.

While you are taking Enlafax XR

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (such as electrocardiogram (ECG) or blood tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Enlafax XR.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. Enlafax XR may affect other medicines used during surgery.

If you are about to have any urine tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep enough Enlafax XR capsules to last weekends and holidays.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Watch carefully for signs that your depression or anxiety is getting worse, especially in the first few weeks of treatment, or if your dose has changed.

Sometimes people with depression can experience a worsening of their depressive symptoms. This can happen even when taking an antidepressant.

Information from clinical trials has suggested that children, adolescents and young adults (18-24 years), particularly those with depression, may be at increased risk of suicidal behaviour (including suicide attempts) when treated with venlafaxine, especially during initial treatment.

Tell your doctor immediately if you experience any of the following symptoms, especially if they are severe, you have not had these symptoms before or they may happen suddenly.

- anxiety or agitation
- panic attacks
- difficulty sleeping
- irritability
- aggressiveness
- hostility or impulsiveness
- restlessness
- overactivity or uninhibited behaviour
- other unusual changes in behaviour
- thoughts of suicide.

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

Warning signs of suicide

If you or someone you know is showing the following warning signs, either contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment.

All thoughts or talk about suicide or violence are serious.

- thoughts or talk about death or suicide
- thoughts or talk about self-harm or doing harm to others
- any recent attempts of self-harm
- an increase in aggressive behaviour, irritability, or agitation.

Things you must not do

Do not take Enlafax XR to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as

- headache
- nausea and vomiting
- dizziness
- insomnia
- nervousness
- anxiety
- confusion and agitation
- diarrhoea
- sweating
- loss of appetite
- tremor
- flu-like symptoms
- impaired coordination and balance
- tingling or numbness of the hands and feet.

Slowly reducing the amount of Enlafax XR being taken reduces the possibility of these effects occurring.

Some of these symptoms may impair driving, or the operation of dangerous machinery. Avoid

these activities if you experience these symptoms.

Things to be careful of

Be careful driving or operating machinery until you know how Enlafax XR affects you.

This medicine may cause drowsiness and un-coordination in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Enlafax XR like other medicines in this class, may increase your risk of bone fracture.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol drowsiness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Enlafax XR. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking this medicine, effects of your condition, or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Stomach, bowel or urinary tract problems:
 - nausea
 - vomiting
 - loss of appetite
 - diarrhoea

- constipation
- difficulty passing urine
- passing urine frequently or incontinence
- changes in your behaviour:
 - difficulty sleeping or abnormal dreams
 - paranoia
 - aggression
 - sexual function problems: such as delayed ejaculation, problems with erection, decreased sex drive or difficulties achieving orgasm (In some cases, these symptoms have continued after stopping treatment)
 - nervousness
 - teeth grinding
 - impaired coordination and balance
- difficulty thinking or working because of:
 - yawning
 - feeling sedated or drowsy
 - fainting or dizziness after standing up
 - restlessness or difficulty sitting still
 - headache
 - rapid heart beat
 - heavy or irregular menstrual periods
- sweating
- hot flushes
- rash
- hair loss
- itchiness
- weight loss
- weight gain
- flow of milk in women who are not breastfeeding
- blurred vision
- ringing in the ears
- altered taste
- dry mouth.

Tell your doctor as soon as possible if you notice any of the following:

- muscle tremors, spasms, twitching, jerky movements or sustained muscle contractions
- abnormal facial movements such as tongue thrusting, repetitive chewing, jaw swinging, or grimacing
- a feeling of apathy or not caring about things

- hallucinations
- agitation
- confusion
- unusually overactive
- changes in muscle tone, muscle weakness or fatigue
- numbness or pins and needles
- problems with breathing, shortness of breath
- cough
- bleeding or bruising more easily than normal
- sensitivity to sunlight.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fits or seizures, which may be accompanied by a sudden fever
- signs of allergy such as rash or hives, swelling of the face, lips, tongue or throat, wheezing or difficulty breathing or swallowing
- symptoms of sudden fever with sweating, rapid heartbeat and muscle stiffness, which may lead to loss of consciousness
- palpitations, shortness of breath, intense chest pain, or irregular heartbeats
- dark, red or cola-coloured urine, muscle weakness and tenderness, stiffness or aching
- stomach pain, nausea, fever, clammy skin and sweating
- yellowing of the skin or eyeballs, fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements
- a severe skin reaction with painful red areas and large blisters, accompanied by fever and chills, aching muscles and generally feeling unwell
- symptoms of a high fever, agitation, confusion, trembling and abrupt contractions of muscles
- signs of an infection such as severe chills, fever, sore throat and mouth ulcers

- black sticky bowel motions or bloody diarrhoea.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are usually rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (for example, increase in blood pressure or blood cholesterol) can only be found when your doctor does tests from time to time to check your progress.

After taking Enlafax XR

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store Enlafax XR or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

There are three strengths of Enlafax XR capsules:

- Enlafax XR 37.5 mg - white opaque capsules containing one 37.5 mg tablet. Capsule printed with 'VEN' on cap and '37.5' on body.
- Enlafax XR 75 mg – flesh opaque capsules containing two 37.5 mg tablets. Capsule printed with 'VEN' on cap and '75' on body.
- Enlafax XR 150 mg – scarlet opaque capsules containing three 50 mg tablets. Capsule printed with 'VEN' on cap and '150' on body.

Ingredients

Active Ingredient(s):

Enlafax XR contains 37.5 mg, 75 mg or 150 mg of venlafaxine hydrochloride as the active ingredient.

Inactive ingredient(s): Enlafax XR contains:

- hypromellose,
- eudragit E12.5
- eudragit RS 100
- sodium lauryl sulfate
- magnesium stearate
- titanium dioxide (E171)
- gelatin
- black ink

Enlafax XR 75 mg only:

- iron oxide red (E172)

Enlafax XR 150 mg only:

- erythrosine (E172)
- indigo carmine (E132).

Contains sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Viatris Ltd
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Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

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