

EFEXOR®-XR

Venlafaxine hydrochloride modified release 37.5, 75 & 150 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Efexor-XR.

This leaflet answers some common questions about Efexor-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 Efexor-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 Efexor-XR is used for

Efexor-XR is used to treat

- Major depression
- Generalised anxiety disorder
- Social anxiety disorder
- Panic disorder
- Prevention of relapse and recurrence of major depression where appropriate.

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 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.

How it works

Efexor-XR contains the active ingredient venlafaxine hydrochloride. It belongs to a group of medications for depression and anxiety, called Serotonin-Noradrenaline Reuptake Inhibitors (SNRIs).

Serotonin and noradrenaline are chemical messengers that allow certain nerves in the brain to work. Efexor-XR capsules increases the level of these two messengers. Expert thinks this is how it helps to restore your feeling of wellness.

Efexor-XR is not addictive.

Your doctor may have prescribed this medicine for another reason.

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

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

Before you take Efexor-XR

When you must not take it

Do not take Efexor-XR if you have an allergy to:

- any medicine containing venlafaxine hydrochloride.

- any of the ingredients listed at the end of this leaflet.

Do not take Efexor-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.

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

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children 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.

Your doctor may wish to do some heart test such as an electrocardiogram (ECG) or blood test during treatment with Efexor-XR.

Tell your doctor if you are pregnant or plan to become pregnant.

Efexor-XR is not recommended for use during pregnancy. Your doctor will discuss the risk and benefits of using this medicine if you are pregnant. One of these risks is that newborn babies, whose mother have been taking Efexor-XR in the last few months of pregnancy, may experience problems soon after delivery, including breathing difficulties, seizures and lack of oxygen in their blood.

If you take Efexor-XR or similar antidepressants mid to late in your pregnancy, you may develop a condition known as “pre-eclampsia”, which is characterized by persistent high blood pressure during or after pregnancy. Symptoms of pre-eclampsia can include headaches, abdominal pain, shortness of breath or burning behind the sternum, nausea and vomiting, confusion, heightened state of anxiety, and/or visual disturbances such as oversensitivity to light, blurred vision, or seeing flashing spots or auras.

If you take Efexor-XR or similar antidepressants in the last month of your pregnancy, you may experience heavy bleeding during and/or after delivery.

Continuing treatment with Efexor-XR or similar antidepressants during pregnancy should be strictly

as directed by your doctor. Symptoms of a relapse may occur if treatment is discontinued, even if major depression was previously under control.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Efexor-XR passes into breast milk and there is a possibility that the breast-fed baby may be affected. For this reason, the use of Efexor-XR is not recommended in breastfeeding women.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking Efexor-XR.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are taking Efexor-XR.

Some medicines may interfere with Efexor-XR. These include:

- All prescription medicines
- Medicines for weight loss
- All medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Do not start to take any other medicine while you are taking Efexor-XR, unless it is prescribed or approved by your doctor.

Some medicines may interfere with Efexor-XR, or Efexor-XR may interfere with these medicines. 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, tapentadol, 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.

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

- Metoprolol for high blood pressure or angina
- Medicines used to prevent blood clotting such as anti-coagulants and platelet inhibitors
- Indinavir for viral infections
- Antibiotics such as erythromycin and linezolid for bacterial infections
- Ketoconazole or fluconazole for fungal infections.

These medicines may be affected by Efexor-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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Efexor-XR

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

Your doctor will tell you how many capsules you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Depression and Anxiety

The usual starting dose is 75 mg taken once daily. After 2 weeks, your doctor may increase in the dose to 150 mg a day.

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 your dose unless your doctor tells you to.

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

If you have heart problems your doctor may first do some blood tests or heart tests such as an electrocardiogram (ECG) before increasing your dose of Efexor-XR.

How to take it

Take your medicine once daily with food, at approximately the same time each day.

Swallow the capsules whole with a full glass of water or other non-alcoholic liquid.

Do not divide, crush, chew or dissolve the capsule in water.

Do not be concerned if you see small white granules or balls in

your stools after taking Efexor-XR.

Inside Efexor-XR capsules are spheroids or small white balls that contain the venlafaxine active ingredient. These spheroids are released from the capsules 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 stool. Therefore, even though, you may see spheroids in your stools, your dose of venlafaxine has been absorbed.

When to take it

Take your medicine at about the same time each day.

This could be either in the morning or in the evening.

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 Efexor-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 Efexor-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.

While you are taking Efexor-XR

Things you must do

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

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

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

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

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

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

Take Efexor-XR capsules as your doctor has prescribed.

Keep enough Efexor-XR capsules to last weekends and holidays.

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 Efexor-XR, 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 happen very 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 talks about suicide or violence are serious.

- Thoughts of talks 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 Efexor-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 you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. 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 Efexor-XR being taken reduces the possibility of these effects occurring.

Things to be careful of

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

Efexor-XR capsules may make you feel drowsy.

If you are feeling drowsy or are uncoordinated, be careful that you do not fall over.

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

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when

you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Efexor-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:

- Feel sleepy
- Vomit
- Have an increased heart rate or changes in heart rhythm
- Have a seizure (fits)
- Have breathing difficulties
- Become unconscious
- Have dilated pupils

Keep the telephone number for these places handy whilst taking any medications.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Efexor-XR.

This medicine helps most people with depression, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

It can be difficult to tell whether side effects are the results 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 changes in your condition.

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 or vomiting
 - Loss of appetite
 - Diarrhoea
 - Constipation
 - Difficulty passing urine, passing urine more frequently, or urinary 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
 - 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 heartbeat
 - 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

The above list includes the more common side effects of your

medicine.

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

- Muscle tremors, spasm, twitching, jerk 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.

The above list includes serious side effects that may require medical attention.

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, yellowing of the skin, 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 muscle and generally feeling unwell
- Symptoms of a high fever, agitation, confusion, trembling and abrupt contraction 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.

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. Tell your doctor if you notice any other effects.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Efexor-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 30°C.

Do not store Efexor-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 Efexor- XR capsules:

- Efexor-XR 37.5 mg capsules are grey and peach in colour
- Efexor-XR 75 mg capsules are opaque peach in colour
- Efexor-XR 150 mg capsules are opaque dark orange in colour.

Each capsule is printed with a "W" and the capsule strength.

Each blister pack contains 28 capsules.

Ingredients

Active ingredient:

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

Inactive ingredients:

Efexor-XR also contains:

- Iron oxide yellow CI 77492
- Iron oxide red CI 77491
- Cellulose-microcrystalline
- Ethyl cellulose
- Hypromellose
- Gelatin
- Talc, purified
- Titanium dioxide
- Red ink Opacode S-1-15094/S-1- 15095 (37.5 mg and 75 mg strengths)
- White ink TekPrint SB-0007P (150 mg strength)
- Iron oxide black CI 77499 (Efexor-XR 37.5 mg only).

If you want to know more

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

Who supplies this medicine

Efexor-XR is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

08 May 2023.
(Based on datasheet dated 08 May 2023)

Efexor[®]-XR is a Viatrix company trade mark.