

EFEXOR[®] XR CAPSULE

Venlafaxine hydrochloride (37.5 mg, 75 mg, 150 mg)

What is in this leaflet

1. What EFEXOR XR is used for
2. How EFEXOR XR works
3. Before you use EFEXOR XR
4. How to use EFEXOR XR
5. While you are using it
6. Side effects
7. Storage and Disposal of EFEXOR XR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision
11. Serial Number

What EFEXOR XR is used for

EFEXOR XR is an antidepressant. EFEXOR XR capsules are given to people suffering from depression, anxiety disorders or panic disorder.

How EFEXOR XR works

EFEXOR XR belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). Serotonin and noradrenaline are chemical messengers that allow certain nerves in the brain to work. It is thought that people who are depressed and/or anxious may 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.

Before you use EFEXOR XR

- *When you must not use it*

- If you are allergic to venlafaxine or to any of the other ingredients in EFEXOR XR capsules
- 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 (a progressive movement disorder). Also, you must wait at least 7 days after you stop taking EFEXOR XR before you take any MAOI

Pregnancy and lactation

Tell your doctor if you become pregnant, or you are trying to become

pregnant. You should use EFEXOR XR only after discussing the potential benefits and the potential risks to your unborn child with your doctor.

If you are taking this medicine during pregnancy, the baby born might experience some symptoms like not feeding properly, in addition to having breathing difficulties. If your baby has these symptoms when it is born and you are concerned, contact your doctor who will be able to advise you.

EFEXOR XR 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 this medicine.

Increased risk of postpartum hemorrhage following SSRI/SNRI exposure within the month prior to birth.

If you take EFEXOR XR 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 should be aware that you are taking EFEXOR XR so they can advise you.

- *Before you start to use it*

If any of the following apply to you, please tell your doctor before taking EFEXOR XR.

- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- If you have a history of heart problems relating to recent heart attack, increases in heart rate, or heart rhythm problems
- If you have history of high blood pressure
- If you have a history of fits (seizures)
- If you have a history of, or if someone in your family has had, bipolar disorder
- If you have a history of, aggressive behavior

- If you are taking water tablets (diuretics) or dehydrated
- 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
- If you have high cholesterol levels

- *Taking other medicines*

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

In particular tell your doctor if you are taking:

- Other serotonergic medicines together with EFEXOR XR, it could increase the risk of developing serotonin syndrome. Signs and symptoms of serotonin syndrome may include restlessness, hallucinations, loss of coordination, fast heartbeat, increased body temperature, fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea and vomiting. In its most severe form, serotonin syndrome can resemble Neuroleptic Malignant Syndrome (NMS). Signs and symptoms of NMS may include high temperature with rigid muscles, confusion or agitation, and underactive reflexes
- Other medicines to treat depression, for instance MAOIs, (e.g. methylene blue) other SNRIs, selective serotonin reuptake inhibitors (SSRIs), amphetamines, imipramine) or medicines containing lithium
- Triptans (used for migraine)
- Sibutramine or any weight loss agents
- Fentanyl and its analogues, tramadol, tapentadol, meperidine, methadone and pentazocine (used to treat severe pain)
- St. John's Wort (also called *Hypericum perforatum*, a natural or herbal remedy used to treat mild depression)
- Linezolid, an antibiotic (used to treat infections)

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- Dextromethorphan (a cough suppressant)
- Tryptophan (used for problems such as sleep and depression)
- Haloperidol or other antipsychotics or other dopamine antagonists
- Cimetidine (a stomach medicine)
- Ketoconazole (an antifungal medicine)
- Metoprolol (used to treat high blood pressure and heart problems)

Use of EFEXOR XR may result in false-positive urine tests for substances such as phencyclidine (PCP) and amphetamine. False-positive urine tests may be expected for several days after you may have stopped using EFEXOR XR.

How to use EFEXOR XR

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The usual recommended starting dose for treatment of

- depression, and anxiety disorder is 75 mg per day
- panic disorder is a lower dose, 37.5 mg per day

The dose may be increased by your doctor gradually, and if needed, even up to a maximum dose of 375 mg daily for depression or 225 mg for daily anxiety disorder and panic disorder.

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

There is not enough experience with the use of EFEXOR XR in children and adolescents under 18 years.

- When to use it

Take EFEXOR XR with food, at approximately the same time each day. Capsules must be swallowed whole

with fluid and not opened, crushed, chewed or dissolved. Alternatively, EFEXOR XR may be taken by carefully opening the capsule and sprinkling the entire contents on a spoonful of applesauce.

This medicine/food mixture should be swallowed immediately without chewing and followed with a glass of water to ensure complete swallowing of the pellets.

- How long to use it

Do not stop taking your capsules or change the dose without the advice of your doctor even if you feel better. If your doctor thinks that you no longer need EFEXOR XR, he/she will ask you to reduce your dose slowly before stopping treatment altogether. The time period and the amount of dose required for reducing the dose will depend on the dose and duration of your therapy. It may take months or longer to discontinue the medicine.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The symptoms of a possible overdose may include a rapid increase or slowing of heartbeat, low blood pressure, dilated pupils, changes in level of alertness (ranging from

sleepiness to coma), seizures or fits, vomiting, ECG changes, spinning sensation and death.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking EFEXOR XR.

Tell your doctor immediately if you become pregnant while taking this medication.

Contact your doctor if you notice any worsening of your symptoms of depression and anxiety, especially when beginning therapy or changing dosage regimen.

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.

You should avoid alcohol while you are taking EFEXOR XR.

Do not be concerned if you see small white balls or granules in your stools after taking this medicine. Inside EFEXOR XR capsules are spheroids (small white balls) that contain the active ingredient (venlafaxine). These spheroids are released from the capsule into your stomach. Venlafaxine is slowly released as it travels through stomach and intestine. The spheroid "shell" does not dissolve and is passed out in your stools. So, even though you may see spheroids in your stools, your dose of medicine has been absorbed.

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- Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give EFEXOR XR to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or gives you a headache and impairs judgment, thinking, and motor skills, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Some people have experienced the following side effects while taking EFEXOR XR:

Very Common (affects more than or up to 1 in 10 people)

- Headache*
- Inability to sleep
- Dizziness
- Sedation
- Nausea
- Dry mouth
- Constipation
- Excessive sweating

Common (may affect less than 1 in 10 and more than or up to 1 in 100 people):

- Weakness, fatigue, chills*
- Increase in blood pressure, hot flush
- Rapid or strong pounding of heart beat
- Decreased appetite, vomiting, diarrhoea*
- Shortness of breath*
- Rash, severe itching of the skin,* nervousness
- Ringing or buzzing in the ears*

- Lack of taste
 - Weight loss or gain
 - Abnormal dreams, stiff muscles, strange feeling on the skin such as “pins and needles” or burning, trembling.
 - Restlessness and inability to remain still*
 - Yawning
 - Night sweats*
 - Visual disturbance including dilated pupils, inability of the eye to focus
 - Change in sexual function, e.g. abnormal ejaculation in men, lack of orgasm, reduced sex drive
 - Difficulties passing urine, frequent urination*
- * Side effects identified from post-marketing reports.

Side effects such as aggression, suicidal thoughts, are known to occur when people either reduce or stop using this medicine, especially when it is stopped suddenly or the dose is reduced too quickly. Some people may experience symptoms such as stated above. Rarely, poor co-ordination and balance, shaking, seizures, or flu-like symptoms.

The discontinuation effects could be extended for a longer time or may become serious. Therefore, you should never stop your dose suddenly, take advice of your doctor before stopping the dose. Sometimes, it may take months or longer to discontinue the medicine.

There have been reports of long-lasting change in sexual function where the symptoms have continued even after discontinuation of the medicine.

Also, you should know that children (aged 6 to 17) have an increased risk of side effects, such as suicidal thoughts and hostility, self-harm, abdominal pain, agitation, indigestion, bruising, nosebleed and pain in the muscles.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines

(AEFI)]

Storage and Disposal of EFEXOR XR

- Storage

Store below 30°C.

Keep out of reach of children.

Store in place that is not exposed to light.

- Disposal

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.

Product Description

- What it looks like

Efexor[®] XR 37.5 mg:
Hard gelatin capsule, opaque light grey cap and opaque peach body branded with a flying “W” on the cap and “37.5” on the body with red ink, containing white to off-white spheroids of about 1 mm in diameter. 1 blister strip containing 7 capsules each.

Efexor[®] XR 75 mg:
Hard gelatin capsule, opaque light peach cap and body branded with a flying “W” on the cap and “75” on the body in red ink, containing white to off-white spheroids of about 1 mm in diameter.

1 blister strip containing 14 capsules each.

2 blister strips containing 14 capsules each.

Efexor[®] XR 150 mg:
Elongated hard gelatin capsule, opaque dark orange cap and body branded with flying “W” on cap and ‘150’ on body in white ink containing white to off-white spheroids of about 1 mm in diameter.

1 blister strip containing 14 capsules

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each.

2 blister strips containing 14 capsules

each.

- Ingredients**- Active ingredient**

Venlafaxine hydrochloride

- Inactive ingredientsMicrocrystalline cellulose,
hydroxypropyl methylcellulose,
ethyl cellulose.

Capsule contains:

Gelatin, iron oxides (E172), titanium
dioxide (E171) and printing ink.**- MAL numbers:**

Product Name	Registration Number
Efexor XR 37.5 mg Capsule	MAL06030815ACRZ
Efexor XR 75 mg Capsule	MAL20002460ACRZ
Efexor XR 150 mg Capsule	MAL20002459ACRZ

ManufacturerPfizer Ireland Pharmaceuticals Unlimited
Company
Little Connell, Newbridge,
Ireland.**Product Registration Holder**Viatrix Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.**Date of Revision**

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