

EFEXOR(R)-XR

Venlafaxine Hydrochloride Modified Release Capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Efexor-XR capsules. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist or asking questions.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Efexor-XR against the expected benefits it will have for you.

If you have any questions about Efexor-XR, ask your doctor or pharmacist.

Keep this leaflet with your Efexor-XR capsules.

You may need to read it again.

What Efexor-XR is for

The name of your medicine is Efexor-XR. It contains the active ingredient called venlafaxine hydrochloride.

Efexor-XR capsules are used in the treatment and prevention of relapse of depression and panic attacks and in the treatment of 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.

Efexor-XR capsules belong to a class 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 increase the level of these two messengers. Experts think this is how it helps to restore your feeling of wellness.

Efexor-XR is not addictive.

Your doctor may have prescribed Efexor-XR capsules for another purpose. Ask your doctor if you have any questions about why Efexor-XR capsules has been prescribed for you.

Before you take Efexor-XR

When you must not take Efexor-XR

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.

Do not take Efexor-XR if you are allergic to it or to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction include:

- * Skin rash
- * Itching or hives on the skin
- * Swelling of the face, lips, tongue, throat or other parts of the body
- * Shortness of breath, wheezing or troubled breathing; difficulty swallowing

Do not give Efexor-XR to children or adolescents under 18 years of age.

The safety and effectiveness of Efexor-XR in this age group have not been established.

Do not use Efexor-XR after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well as it should.

Do not use Efexor-XR if the packaging is torn or shows signs of tampering.

Before you start to take Efexor-XR

Tell your doctor or pharmacist if you have allergies to the active ingredient or any of the other ingredients listed at the end of this leaflet.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Efexor-XR is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of using Efexor-XR if you are pregnant. One of these risks is that newborn babies, whose mothers 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.

Tell your doctor or pharmacist if you are breast-feeding or planning to breast-feed.

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 breast-feeding women.

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

- * A history of fits (seizures or convulsions)
- * A personal history or family history of bipolar disorder
- * A history of aggression
- * Blood pressure problems
- * Glaucoma (increased pressure in the eye)
- * A tendency to bleed more than normal
- * Raised cholesterol levels
- * Problems with your kidneys or liver
- * Problems with your heart

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

- * Any other medical conditions.

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 take Efexor-XR.

Taking other medicines

Tell your doctor or pharmacist if you take any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop, such as St Johns Wort or tryptophan supplements.

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 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
- * Haloperidol, risperidone, lithium or clozapine (used to treat mental disorders)
- * Tramadol (a pain killer)
- * Cimetidine (used to treat reflux and stomach ulcers)
- * Triptans (used to treat migraine)
- * Amiodarone or quinidine (used to treat irregular heart beats)

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

- * Indinavir (an antiviral)

- * Medicines used to prevent blood clotting such as anti-coagulants and platelet inhibitors
- * Erythromycin and linezolid (used to treat infections)
- * Ketoconazole or fluconazole (used as antifungal medicines)
- * Medications for weight loss, including sibutramine
- * Metoprolol (used to treat high blood pressure or angina).

You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Efexor-XR.

How to take Efexor-XR

Swallow the capsules whole with a glass of water or other non-alcoholic liquid. Do not divide, crush, chew or dissolve the capsules 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 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.

How much to take

The usual starting dose is 75mg taken once daily. For panic attacks, treatment is usually started with a dose of 37.5 mg once daily for the first 4 to 7 days. After that time the

dose should be increased to 75 mg once daily. If necessary, after two weeks, your doctor may increase your dose.

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 and your doctor wishes to increase your dose of Efexor-XR, your doctor may first do some blood tests or heart tests such as an electrocardiogram (ECG).

When to take it

Efexor-XR should be taken once daily with food, at approximately the same time each day.

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

Avoid drinking alcohol while you are using Efexor-XR.

How long to take Efexor-XR

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.

Even when you feel well again, you may need to keep taking Efexor-XR for several months to make sure the benefits last. Discuss this with your doctor and don't stop taking Efexor-XR until gaining your doctor's agreement.

If you forget to take Efexor-XR

If it is less than 12 hours until your next dose, skip the dose you missed and then take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking as you would normally.

Do not take a double dose to make up for the dose you missed. Contact your doctor if you have missed more than two doses in a row.

Always finish the capsules you are taking in the current pack before you start a new pack.

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

If you take too much (overdose)

It is important that you do not take more Efexor-XR capsules than your doctor has prescribed. If you do take more than you have been prescribed, contact your doctor immediately for advice.

If anyone accidentally swallows any Efexor-XR capsules, call your nearest Poisons Information Centre for advice (Tel: 13 11 26), or go to Accident and Emergency at your nearest hospital. Keep the telephone number for these places handy whilst taking any medications.

If you take too many Efexor-XR capsules you may:

- * 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.

While you are taking Efexor-XR

Things you must do

Visit your doctor regularly for a check up. Always discuss any questions you have about Efexor-XR capsules with your doctor.

Take Efexor-XR capsules as your doctor has prescribed.

Keep enough Efexor-XR capsules to last weekends and holidays. You need a prescription from your doctor to get more Efexor-XR capsules.

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) during treatment 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

All thoughts or talk about suicide or violence are serious. 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:

- * 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 to be careful of

Efexor-XR capsules may make you feel drowsy. Be careful driving or operating dangerous machinery until you know how it affects you.

Things you must not do

Do not suddenly stop taking Efexor-XR capsules if you have been taking it for some time.

Check with your doctor for the best way to slowly reduce the amount of Efexor-XR you are taking before stopping completely.

Side effects from stopping treatment with Efexor-XR may include:

- * 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.

Some of these symptoms may impair driving, or the operation of dangerous machinery. These activities should be avoided if you experience these symptoms.

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

Side effects

All medicines can have side effects. Sometimes they are serious; often they are not.

Tell your doctor if you develop any of the following side effects or if they become troublesome.

Stomach, bowel or urinary tract problems such as:

- * Nausea or vomiting
- * Loss of appetite
- * Diarrhoea
- * Constipation
- * Difficulty passing urine, passing urine more frequently, or urinary incontinence.

Changes in your behaviour such as:

- * Difficulty sleeping or abnormal dreams
- * Sexual function problems such as delayed ejaculation, problems with erection, decreased sex drive or difficulties achieving orgasm
- * Nervousness
- * Teeth grinding
- * Muscle tremors, spasms, twitching, jerky movements or sustained muscle contractions
- * Impaired coordination and balance
- * 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.

Difficulty thinking or working because of:

- * Yawning
- * Feeling sedated or drowsy
- * Fainting or dizziness after standing up
- * Changes in muscle tone
- * Muscle weakness or fatigue
- * Restlessness or difficulty sitting

still

- * Headache
- * Rapid heart beat
- * Problems with breathing
- * Heavy or irregular menstrual periods.

Changes in your appearance such as:

- * Sweating (including night sweats)
- * Hot flushes
- * Rash
- * Hair loss
- * Itchiness
- * Weight loss or weight gain
- * Flow of milk in women who are not breastfeeding
- * Bleeding or bruising more easily than normal.

In some people, Efexor-XR may lead to changes in the way your blood clots.

Changes in your sight, hearing, taste or touch such as:

- * Blurred vision
- * Dilated pupils
- * Visual disturbances
- * Sensitivity to sunlight.
- * Ringing in the ears
- * Altered taste
- * Dry mouth
- * Numbness or pins and needles.

Other changes you may not be aware of:

- * Increased blood pressure
- * Increase in blood cholesterol levels.

Tell your doctor immediately, or go to your nearest hospital if you notice any of the following:

- * 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 heart beat and muscle stiffness, which may lead to loss of consciousness

- * Palpitations, fainting, shortness of breath or chest pain
- * 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 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.

These symptoms are usually rare but may be serious and need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

After using Efexor-XR

Storage

Keep your Efexor-XR capsules in their blister pack until it is time to take them.

The capsules may not last as well if you take them out of the blister pack.

Keep Efexor-XR capsules in a cool dry place where the temperature stays below 30 degrees C.

Do not store Efexor-XR capsules

or any other medicine in the bathroom or near a sink. Do not leave Efexor-XR capsules in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep Efexor-XR capsules and all medication where young 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

Return any unused medicine to your pharmacist.

Product Description

What Efexor-XR looks like

There are three strengths of Efexor-XR capsules, containing 37.5 mg, 75 mg or 150 mg of venlafaxine in an extended release formulation, which allows for once-a-day dosing.

The 37.5 mg capsules are grey and peach in colour. The 75 mg capsules are opaque peach in colour and the 150 mg capsules are opaque dark orange. The capsules are printed with a "W" and the capsule strength.

Efexor-XR 37.5 mg, 75 mg and 150 mg are available in blister packs containing 28 capsules.

Ingredients

Efexor-XR capsules contain venlafaxine hydrochloride as the active ingredient.

Efexor-XR 37.5 mg, 75 mg and 150 mg capsules contain the following inactive ingredients:

- * 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 (37.5mg and 75mg strengths)
- * White ink TekPrint SB-0007P (150mg strength).

In addition to these, Efexor-XR 37.5 mg capsules also contain iron oxide black CI 77499.

Efexor-XR does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Efexor-XR capsules are supplied by:

Wyeth Australia Pty Limited

ABN: 16 000 296 211

17-19 Solent Circuit,

Norwest Business Park,

Baulkham Hills, NSW 2153.

Telephone: (02) 8850 8200 or (02) 9761 8200

For further information please contact Wyeth Australia on toll-free 1800 500 498 or E-mail: medinfo@wyeth.com

Australian Registration Numbers:

37.5 mg blister packs:

AUST R 99802

75 mg blister packs:

AUST R 60858

150 mg blister packs:

AUST R 60859

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