

PACKAGE LEAFLET: INFORMATION FOR USER

Efexor® XL 150mg prolonged-release capsules, hard (venlafaxine (as hydrochloride))

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Efexor XL 150mg prolonged-release capsules, hard, but will be referred to as Efexor XL throughout this leaflet. Please note that this leaflet also contains about other strengths such as Efexor XL 37.5mg and 75mg prolonged-release capsules, hard.

In this leaflet:

1. What Efexor XL is and what it is used for
2. Before you take Efexor XL
3. How to take Efexor XL
4. Possible side effects
5. How to store Efexor XL
6. Further information

1. WHAT EFEXOR XL IS AND WHAT IT IS USED FOR

Efexor XL 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.

Efexor XL is a treatment for adults with depression. It 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. BEFORE YOU TAKE EFEXOR XL

Do not take Efexor XL

- If you are allergic to venlafaxine or any of the other ingredients of this medicine (Section 6 contains a full list).
- 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. Taking an irreversible MAOI together with Efexor XL, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking Efexor XL before you take any MAOI (see also the section entitled "Taking other medicines" and the information in that section about 'Serotonin Syndrome').

Take special care with Efexor XL

If any of the following apply to you, please tell your doctor **before** taking Efexor XL:

- If you use other medicines that taken together with Efexor XL 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 been told you have an abnormal heart rhythm.
- 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 taking other medicines that may increase the risk of bleeding e.g., warfarin (used to prevent blood clots).
- 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.

Efexor XL may cause a sensation of restlessness or an inability to sit or stand still during the first few weeks of treatment. You should tell your doctor if this happens to you.

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 tooth decay (caries). Therefore, you should take special care in your dental hygiene.

Diabetes

Your blood glucose levels may be altered due to Efexor XL. Therefore, the dosage of your diabetes medicines may need to be adjusted.

Use in children and adolescents under 18 years of age

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

Taking other medicines

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 Efexor XL 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 Efexor XL**. Tell your doctor if you have taken these medicines within the last 14 days. (MAOIs: see the section "Before you take Efexor XL").

• **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)
- Other medicines to treat depression, for instance SNRIs, SSRIs, tricyclics, or medicines containing lithium
- Medicines containing linezolid, an antibiotic (used to treat infections)
- Medicines containing moclobemide, a MAOI (used to treat depression)
- Medicines containing sibutramine (used for weight loss)
- Medicines containing tramadol, fentanyl, tapentadol, pethidine, or pentazocine (used to treat severe pain)
- Medicines containing dextromethorphan (used to treat coughing)
- Medicines containing methadone (used to treat opioid drug addiction or severe pain)
- Medicines containing methylene blue (used to treat high levels of methaemoglobin in the blood)
- 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 heart beat, 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 heart beat, sweating, severe muscle stiffness, confusion, increased muscle enzymes (determined by a blood test).

Tell your doctor immediately, or go to the casualty department at your nearest hospital if you think serotonin syndrome is happening to you.

You must tell your doctor if you are taking medicines that can affect your heart rhythm.

Examples of these medicines include:

- Antiarrhythmics such as quinidine, amiodarone, sotalol or dofetilide (used to treat abnormal heart rhythm)
- Antipsychotics such as thioridazine (See also Serotonin syndrome above)
- Antibiotics such as erythromycin or moxifloxacin (used to treat bacterial infections)
- Antihistamines (used to treat allergy)

The following medicines may also interact with Efexor XL 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)

Taking Efexor XL with food and drink

Efexor XL should be taken with food (see section 3 "HOW TO TAKE EFEXOR XL").

You should avoid alcohol while you are taking Efexor XL.

Pregnancy and breast-feeding

Tell your doctor if you become pregnant, or you are trying to become pregnant. You should use Efexor XL 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 Efexor XL. 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 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.

Efexor XL 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.

Driving and using machines

Do not drive or use any tools or machines until you know how this medicine affects you.

3. HOW TO TAKE EFEXOR XL

Always take Efexor XL 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 75mg per day. The dose can be raised by your doctor gradually, and if needed, even up to a maximum dose of 375mg daily for depression. If you are being treated for panic disorder, your doctor will start with a lower dose (37.5mg) and then increase the dose gradually. The maximum dose for generalised anxiety disorder, social anxiety disorder and panic disorder is 225mg/day.

Take Efexor XL 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.

Efexor XL should be taken with food.

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

Do not stop taking this medicine without talking to your doctor (see the section "If you stop taking Efexor XL").

If you take more Efexor XL than you should

Call your doctor or pharmacist immediately if you take more of this medicine than the amount prescribed by your doctor.

The symptoms of a possible overdose may include a rapid heart beat, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

If you forget to take Efexor XL

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 Efexor XL that has been prescribed for you in one day.

If you stop taking Efexor XL

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 Efexor XL, he/she may ask you to reduce your dose slowly before stopping treatment altogether.

Side effects are known to occur when people stop using this medicine, especially when it 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 Efexor XL 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, Efexor XL can cause side effects, although not everybody gets them.

If any of the following happen, do not take more Efexor XL. **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 heart beat, 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 heart beat, 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, itchiness 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 EFEXOR XL, if you stop taking Efexor XL").
- Prolonged bleeding - if you cut or injure yourself, it may take slightly longer than usual for bleeding to stop.

Do not be concerned if you see small white balls or granules in your stools after taking this medicine. Inside Efexor XL capsules are spheroids (small white balls) that contain the active ingredient (venlafaxine). These spheroids are released from the capsule into your stomach. As they travel through your stomach and intestines, venlafaxine is slowly released. 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.

Complete side effect listing

Very common (affects more than 1 in 10 users)

- Dizziness; headache
- Nausea; dry mouth
- Sweating (including night sweats)

Common (affects 1 to 10 users in 100)

- Appetite decreased
- Confusion; feeling separated (or detached) from yourself; lack of orgasm; decreased libido; nervousness; insomnia; abnormal dreams
- Drowsiness; tremor; pins and needles; increased muscle tonus
- Visual disturbance including blurred vision; dilated pupils; inability of the eye to automatically change focus from distant to near objects
- Ringing in the ears (tinnitus)
- Palpitations
- Increase in blood pressure; flushing
- Yawning
- Vomiting; constipation; diarrhoea
- Increased frequency in urination; difficulties passing urine
- Menstrual irregularities such as increased bleeding or increased irregular bleeding; abnormal ejaculation/orgasm (males); erectile dysfunction (impotence)
- Weakness (asthenia); fatigue; chills
- Increased cholesterol

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

- Hallucinations; feeling separated (or detached) from reality; agitation; abnormal orgasm (females); lack of feeling or emotion; feeling over-excited; grinding of the teeth
- A sensation of restlessness or an inability to sit or stand still; fainting; involuntary movements of the muscles; impaired coordination and balance; altered taste sensation
- Fast heart beat; feeling dizzy (particularly when standing up too quickly)
- Shortness of breath
- Vomiting blood, black tarry stools (faeces) or blood in stools; which can be a sign of internal bleeding
- 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; bruising; rash; abnormal hair loss
- Inability to pass urine;
- Weight gain; weight loss

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

- Seizures or fits
- Inability to control urination
- Over activity, racing thoughts and decreased need for sleep (mania)

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
- Swollen face or tongue, shortness of breath or difficulty breathing, often with skin rashes (this may be a serious allergic reaction)
- Excessive water intake (known as SIADH)
- Decrease in blood sodium levels
- Suicidal ideation and suicidal behaviours; cases of suicidal ideation and suicidal behaviours have been reported during venlafaxine therapy or early after treatment discontinuation (see section 2, "Before you take Efexor XL")
- Disorientation and confusion often accompanied by hallucination (delirium); aggression
- 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 serotonin syndrome; stiffness, spasms and involuntary movements of the muscles
- Severe eye pain and decreased or blurred vision
- Vertigo

- Decrease in blood pressure; abnormal, rapid or irregular heart beat, which could lead to fainting; unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins)
- 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)
- Itchiness, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis); slight changes in blood levels of liver enzymes
- Skin rash, which may lead to severe blistering and peeling of the skin; itching; mild rash
- Unexplained muscle pain, tenderness or weakness (rhabdomyolysis)
- Abnormal breast milk production

Efexor XL sometimes causes unwanted effects that you may not be aware of, such as increases in blood pressure or abnormal heart beat; slight changes in blood levels of liver enzymes, sodium or cholesterol. More rarely, Efexor XL 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 Efexor XL for a long time.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE EFEXOR XL

Keep out of the reach and sight of children.

Do not use after the expiry date, which is stated on the pack after 'Exp'. The date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

If your capsule become discoloured or show any signs of deterioration, you should seek the advice of your pharmacist.

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.

6. FURTHER INFORMATION

What Efexor XL contains

The active substance is venlafaxine.

Each prolonged-release capsule contains 150mg venlafaxine (as hydrochloride).

The other ingredients are: microcrystalline cellulose, ethylcellulose, hydroxypropylmethylcellulose, red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171), gelatin and printing ink (shellac, ethyl alcohol, butyl alcohol, isopropyl alcohol, propylene glycol, sodium hydroxide, titanium dioxide and polyvinylpyrrolidone).

What Efexor XL looks like and contents of the pack

The capsules are hard gelatin capsule, opaque and dark orange with 'W' and '150' printed in white, containing white or whitish spheroids approximately 1mm in diameter. Efexor XL is available in blister packs containing 30 capsules.

Manufactured by: Wyeth Medica Ireland, Little Connell, Newbridge, Co. Kildare, Ireland.

Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Efexor® XL 150mg prolonged-release capsules, hard PPA No: 1328/118/003

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Efexor is a registered trademark of Wyeth Farma.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Efectin ER 37,5 mg Kapseln Efectin ER 75 mg Kapseln Efectin ER 150 mg Kapseln	Latvia	Efexor XR Efexor XR 75 Efexor XR 150
Belgium, Luxembourg	Efexor-Exel 37,5 Efexor-Exel 75 Efexor-Exel 150	Denmark, Finland, Iceland, Norway, Sweden	Efexor Depot
Bulgaria	Efectin ER 75 mg Efectin ER 150 mg	France	Effexor L.P.
Czech Republic	Efectin ER 37.5 mg Efectin ER 75 mg Efectin ER 150 mg	Germany	Trevilor retard 37,5 mg Trevilor retard 75 mg Trevilor retard 150 mg
Cyprus, Greece, Estonia, Lithuania, Portugal	Efexor XR	Ireland, Malta, United Kingdom	Efexor XL
The Netherlands	Efexor XR 37,5 Efexor XR 75 Efexor XR 150	Romania	Efectin EP 37.5 mg Efectin EP 75 mg Efectin EP 150 mg
Italy	Efexor Faxine	Slovenia	Efectin ER 37,5 mg trde kapsule s podaljšanim sproščanjem Efectin ER 75 mg trde kapsule s podaljšanim sproščanjem Efectin ER 150 mg trde kapsule s podaljšanim sproščanjem
Poland	Efectin ER 37,5 Efectin ER 75 Efectin ER 150	Spain	Vandral Retard 75 mg cápsulas de liberación prologada Vandral Retard 150 mg cápsulas de liberación prologada