

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

EFEXOR® XR 75 mg (Capsules)

EFEXOR® XR 150 mg (Capsules)

Venlafaxine

Read all of this leaflet carefully before you start taking EFEXOR XR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **EFEXOR XR** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT EFEXOR XR CONTAINS:

The name of your medicine is EFEXOR XR. The active ingredient in these capsules is venlafaxine hydrochloride. EFEXOR XR capsules contain either 75 mg or 150 mg of venlafaxine base as the hydrochloride salt, in a slow release formulation which means you only need to take your medicine once a day.

EFEXOR XR capsules also contain microcrystalline cellulose, hydroxypropylmethylcellulose and ethylcellulose. The capsule shells contain gelatine, talc, titanium dioxide and the colourants, red iron oxide and yellow iron oxide.

2. WHAT EFEXOR XR IS USED FOR:

EFEXOR XR is an antidepressant and one of a group of medicines called serotonin noradrenaline reuptake inhibitors (SNRIs). It is thought that people who are depressed may have lower levels of serotonin and noradrenaline in their brain. Whilst it is not fully understood how antidepressants work,

EFEXOR XR may help to relieve the symptoms of depression or anxiety by increasing the levels of these substances in the brain.

You have been given EFEXOR XR capsules because you are suffering from the symptoms of depressive illness or have been suffering from anxiety and uncontrollable worry for several months or more (called generalised anxiety disorder), or because you avoid, are afraid of or worry about social situations which can cause you severe anxiety and distress (known as social anxiety disorder or social phobia).

EFEXOR XR is a treatment which can relieve these symptoms and help you get better.

3. BEFORE YOU TAKE EFEXOR XR:

Do not take EFEXOR XR:

- If you are allergic to venlafaxine or to any of the other ingredients in EFEXOR XR capsules
- If you have had serious problems with your heart rhythm (ask your doctor if you are not sure)
- If you have moderate or severe heart failure (ask your doctor if you are not sure)
- If you have high blood pressure which is not properly controlled
- If you are taking or have recently taken (within the last two weeks) another antidepressant drug known as a monoamine oxidase inhibitor (MAOI)
- If you are under 18 years of age (please see below)

If any of these apply to you, or if your doctor has prescribed EFEXOR XR for you (or your child) and you want to discuss this, please go back to your doctor before taking EFEXOR XR.

EFEXOR XR is not recommended for use in children and adolescents under the age of 18 years.

EFEXOR XR should not be used for children and adolescents under 18 years because it has not been proven to be an effective medicine in this age-group. Also, patients under 18 years may have an increased risk of side effects such as suicidal thoughts and harming themselves when they take EFEXOR XR.

You should tell your doctor or pharmacist if:

- You have any of the following medical conditions:
 - Liver or kidney disease. Your dose of EFEXOR XR may be lowered

- Heart problems, such as a previous heart attack (ask your doctor if you are not sure)
- You suffer from, or have a history of, mania (feeling high, or over-excited)
- You have had epilepsy, seizures, fits or convulsions. Your doctor will supervise you carefully while you are taking EFEXOR XR
- You have eye problems or suffer from, or have a history of, glaucoma
- You have a low platelet count
- You have a history of drug abuse
- You are taking any of the following medicines:
 - Selective serotonin reuptake inhibitors (SSRIs) or lithium
 - Cimetidine (a stomach medicine) and are elderly or have liver problems, since cimetidine might increase the effect of EFEXOR XR
 - Migraine medicines known as triptans
 - Warfarin (blood thinner)
 - Haloperidol, clozapine or other medicines for schizophrenia
 - Aspirin regularly
 - AIDS or HIV medication
 - Medication to help you lose weight
 - Any other medicines: certain medicines can affect the way EFEXOR XR passes through your body (e.g. ketoconazole, erythromycin)
 - Medicines you have bought without a prescription or herbal remedies
- You are having electroconvulsive therapy (ECT) for depression

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 first starting 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 or harming yourself.

- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years 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.

Pregnancy and Breastfeeding:

If you are already taking EFEXOR XR and have just found out you are pregnant, you should talk to your doctor immediately.

If you are a woman of child-bearing age, you are recommended to use contraception whilst taking EFEXOR XR. You should not use EFEXOR XR during pregnancy.

EFEXOR SR is excreted in human milk therefore you should not breastfeed when you are on treatment with EFEXOR XR.

Driving and using machinery:

Possible side effects of EFEXOR XR include confusion, dizziness and blurred vision. If you get these side effects do not drive or use machinery.

EFEXOR XR and alcohol:

You should avoid alcohol while you are taking EFEXOR XR.

4. HOW TO TAKE EFEXOR XR:

The usual recommended dose for EFEXOR XR is 75 mg, given once daily. If after several weeks further clinical improvement is required, the dose may be increased to 150 mg, given once daily. If needed, the dose can be further increased up to 225 mg given once daily. Dose increments should be made at intervals of approximately 2 weeks or more, but not less than 4 days. The dose for depressed patients may be further increased, if needed, up to 375 mg, given once daily.

It is recommended that EFEXOR XR be taken with food. Each capsule should be swallowed whole with fluid. Do not divide, crush, chew or place capsule in water.

EFEXOR XR should be administered once daily, at approximately the same time either in the morning or in the evening. The extended-release formulation contains spheroids, which release the medicine slowly into the digestive tract. The insoluble portion of these spheroids is eliminated and may be seen in stools.

If you take more EFEXOR XR than you should:

If you take too many capsules you must seek immediate medical attention, even if you feel well, because of the risk of serious side effects. Remember to take the packet with you, even if it is empty.

If you forget to take EFEXOR XR:

Don't worry if you forget to take a capsule. You can take it up to 12 hours after you usually take it; then take your next capsule at the usual time. If the period after the missed dose is more than 12 hours, you should miss the dose altogether and just take your next capsule at the usual time.

When and how to stop taking EFEXOR XR:

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. This should help reduce the chance of withdrawal symptoms. If EFEXOR XR is stopped suddenly or the dose reduced too quickly, some patients may experience symptoms such as tiredness, dizziness, light-headedness, headache, sleeplessness, nightmares, dry mouth, loss of appetite, feeling or being sick, diarrhoea, nervousness, agitation, confusion, tinnitus (ringing in the ears), tingling or rarely electric shock sensations, weakness, poor co-ordination, tremor, sweating or seizures.

Around 3 in 10 patients may notice symptoms on stopping EFEXOR XR but these symptoms are generally mild and disappear within a few days. In rare cases they can be more severe, usually in the first few days of discontinuation, or last longer. Your doctor will advise you on how you should gradually discontinue EFEXOR XR treatment. If you experience any of these or other symptoms which are troublesome, return to your doctor for further advice. Your doctor may ask you to come off your treatment more slowly.

5. POSSIBLE SIDE EFFECTS:

Not all side effects reported for EFEXOR XR are included in this leaflet. Should your general health worsen while taking EFEXOR XR, please consult your doctor, pharmacist or other health care professional for advice.

EFEXOR XR may cause side effects in some people.

You should seek immediate medical help if you have any of the following symptoms:

- Swollen face or tongue, or shortness of breath or difficulty breathing, often with skin rashes (this may be a serious allergic reaction)
- Seizures, fits or convulsions
- Severe muscle tenderness, stiffness or weakness, especially if accompanied by dark urine (this can be caused by muscle breakdown leading to kidney problems – ‘rhabdomyolysis’)
- Black tarry stools (faeces), which can be a sign of internal bleeding
- Severe abdominal or back pains (which could indicate a serious problem in the gut, liver or pancreas)
- 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 serotonergic syndrome
- Frequent or unusual bruising or bleeding, such as nose bleeds (this could indicate that EFEXOR XR has had an effect on your blood, and this may need to be tested)
- Feeling ‘high’ or very over-excited (mania or hypomania)
- Rapid or irregular heartbeat, flushing or fainting

Other possible side effects:

In addition, if any of the following symptoms are severe or become troublesome, you should tell your doctor:

- Feeling sick, constipation
- Headache, unusual tiredness or weakness, sweating, dizziness, dry mouth, difficulty sleeping or drowsiness, nervousness
- Change in sexual function e.g. abnormal ejaculation in men, lack of orgasm

- Change in appetite or bowel habits, diarrhoea, abdominal discomfort, indigestion, being sick, weight loss or gain
- Chills, fever, palpitations
- Agitation, confusion, abnormal dreams
- Sore muscles or painful joints, tremor
- Skin rash, strange feeling on the skin such as “pins and needles” or burning
- Feeling the need to go to the toilet more often than usual
- Reduced sex drive, impotence, menstrual disturbances in women
- Blurred vision, tinnitus (ringing in the ears)
- Difficulty in breathing (dyspnoea) or yawning
- Clenching or grinding of teeth, muscle spasm
- Hallucinations
- Difficulty in urinating
- Increased sensitivity of your skin to sunlight, abnormal hair loss
- Altered taste sensation
- Feeling dizzy or unsteady on standing due to a fall in blood pressure (especially for elderly patients)
- Feeling aggressive or having aggressive thoughts – this is more likely at the start of, and after stopping, treatment
- Itchiness, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis)
- Stiff muscles, rarely clumsiness or loss of balance, slurring or difficulty speaking
- Abnormal breast milk production
- Severe skin rash which may lead to blistering and peeling of the skin
- Feeling of restlessness or if you feel unable to sit or stand still
- Disorientation and confusion often accompanied by hallucination (delirium)

You should also tell your doctor if you have any other unwanted effect not mentioned above.

EFEXOR XR sometimes causes side effects which 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

rarely cholesterol. More rarely, EFEXOR XR may reduce the number 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 XR for a long time.

Tell your doctor or pharmacist you are taking EFEXOR XR before taking any other medicine, if you become pregnant, or you enter hospital for treatment.

After taking EFEXOR XR, you may see very small granular parts of the capsules in your stools.

6. STORING AND DISPOSING OF EFEXOR XR:

You should not use this medicine after the expiry date shown on the packaging.

Keep your EFEXOR XR capsules at room temperature (at or below 25 °C) in a dry place.

Keep this medicine in a safe place where children cannot reach or see it. Your medicine could harm them.

If your doctor decides to stop treatment, return any leftover capsules to your pharmacist. Only keep them if your doctor tells you to.

REMEMBER this medicine is only for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

7. PRESENTATION OF EFEXOR XR:

EFEXOR XR 75 mg: White opaque plastic bottles containing 50 capsules. Blister packaging of 10's (one single blister strip), 30's (three blister strips of 10 each) or 28's (two blister strips of 14 each) packed in a carton box.

EFEXOR XR 150 mg: White opaque plastic bottles containing 50 capsules. Blister packaging of 10's (one single blister strip), 30's (three blister strips of 10 each) or 28's (two blister strips of 14 each) packed in a carton box.

8. IDENTIFICATION OF EFEXOR XR:

EFEXOR XR 75 mg: Size 1 hard gelatine capsule, opaque peach cap and body branded in red ink, containing white to off-white spheroids of about 1 mm diameter.

EFEXOR XR 150 mg: Size 0 elongated hard gelatine capsule, opaque dark orange cap and body branded in white ink, containing white to off-white spheroids of about 1 mm diameter.

9. REGISTRATION NUMBERS:

EFEXOR XR 75 mg: 32/1.2/0318

EFEXOR XR 150 mg: 32/1.2/0319

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

11. DATE OF PUBLICATION:

02 March 2012