PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

EFEXOR® XR 75 mg capsules

EFEXOR® XR 150 mg capsules

Venlafaxine

Sugar free

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, pharmacist, nurse or other health care provider.
- 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.

What is in this leaflet

1. What EFEXOR XR is and what it is used for
2. What you need to know before you take EFEXOR XR
3. How to take EFEXOR XR
4. Possible side effects
5. How to store EFEXOR XR
6. Contents of the pack and other information

1. What EFEXOR XR is and what it 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).

2. What you need to know before you take EFEXOR XR

Do not take EFEXOR XR:

- If you are hypersensitive (allergic) to venlafaxine or to any of the other ingredients of EFEXOR XR (listed in section 6).
- If you are taking or have recently taken (within the last two weeks) another antidepressant, antibiotic or medicine for Parkinson's disease known as a monoamine oxidase inhibitor (MAOI).
- If you are under 18 years of age (see Children and adolescents).
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Do not drink alcohol while being treated with EFEXOR XR as it can lead to extreme tiredness and unconsciousness. Concomitant use with alcohol and/or certain medicines can make your symptoms of depression and other conditions, such as anxiety disorders worse.

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.

Take special care with EFEXOR XR:

- If you use other medicines that taken together with EFEXOR XR could increase the risk of developing serotonin syndrome (see Other medicines and EFEXOR XR).
- If you have eye problems or suffer from, or have a history of, glaucoma.
- If you have heart problems, such as a previous heart attack (ask your doctor if you are not sure).
- 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 have had epilepsy, seizures, fits or convulsions. Your doctor will supervise you carefully while you are taking EFEXOR XR.
- If you suffer from, or have a history of, mania (feeling high, or over-excited).
- If you suffer have a history of aggressive behaviour.
- If you have a history of low sodium levels in your blood (hyponatraemia).
- If you have a low platelet count which can result in bleeding.
- If you have a history of bleeding disorders, or if you are pregnant (see Pregnancy and breastfeeding).
- If you are using weight loss medicines. Using EFEXOR XR and weight loss medicines together is not recommended.
- You should get your cholesterol levels regularly checked if you are on long-term treatment with EFEXOR XR.
- Medicines like EFEXOR XR (so called SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.
- Your blood glucose levels may be altered due to EFEXOR XR. Therefore, the dosage of your diabetes medicines may need to be adjusted.
- False-positive test results for phencyclidine (PCP) and amphetamine have been reported and may be expected for several days after you have stopped using EFEXOR XR.

Children and adolescents

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.

Other medicines and EFEXOR XR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

You should tell your doctor or pharmacist if you are taking any of the following medicines:

- Migraine medicines known as triptans.
- Selective serotonin reuptake inhibitors (SSRIs), other selective serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (used to treat depression or anxiety), amphetamines (used to treat attention deficit hyperactivity disorder [ADHD], narcolepsy and obesity) or lithium.
- Medicines containing sibutramine (used for weight loss).
- Medicines containing tramadol (used to treat severe pain).
- Products containing St. John's Wort (also called *Hypericum perforatum*, a natural or herbal remedy used to treat mild depression).
- Opioids (e.g. buprenorphine) used to treat severe pain or opioid use disorder.
- Medicines containing linezolid, an antibiotic (used to treat infections).
- Medicines containing selegiline (used for Parkinson's disease).
- Products containing tryptophan (used for problems such as sleep and depression).
- AIDS or HIV medication such as indinavir.
- Haloperidol or risperidone (to treat psychiatric conditions).
- Cimetidine (a stomach medicine), and if you are elderly or have liver or renal problems since cimetidine might increase the effect of EFEXOR XR.
- Medicines containing imipramine or desipramine (antidepressants).
- Ketoconazole (an antifungal medicine)
- Metoprolol (a beta blocker to treat high blood pressure and heart problems).

EFEXOR XR with alcohol

You should avoid alcohol while you are taking EFEXOR XR. Do not drink alcohol while being treated with EFEXOR XR. Concomitant use with alcohol can lead to extreme tiredness and unconsciousness

and can make your symptoms of depression and other conditions, such as anxiety disorders worse.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

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

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 or midwife should be aware that you are taking EFEXOR XR so they can advise you.

If you are a woman of childbearing 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 machines

EFEXOR XR may cause effects such as impairment of judgement, thinking and motor skills. Therefore, you should not drive or operate hazardous machinery while taking EFEXOR XR.

It is not always possible to predict to what extent EFEXOR XR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which EFEXOR XR affects them.

3. How to take EFEXOR XR

Do not share medicines prescribed for you with any other person.

Always take EFEXOR XR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

Your doctor will tell you how long your treatment with EFEXOR XR will last. If you have the impression that the effect of EFEXOR XR is too strong or too weak, tell your doctor or pharmacist.

If you take more EFEXOR XR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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.

Overdose can be life-threatening, especially with concomitant use of alcohol and/or certain medicines (see Other medicines and EFEXOR XR).

The symptoms of a possible overdose may include a rapid or slow heartbeat, changes in the electrical activity of your heart which may be seen in tests, low blood pressure, low blood sugar, dizziness, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

If you forget to take EFEXOR XR

Do not take a double dose to make up for forgotten individual doses.

Do not 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.

If you 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 overactive behaviour, anxiety, agitation, nervousness, confusion, sleeplessness, tiredness, drowsiness, tingling or electric shock sensations on the skin, dizziness,

seizures, feeling of falling or spinning, headache, flu-like symptoms, tinnitus (ringing in the ears), poor coordination and balance, tremor, sweating, dry mouth, loss of appetite, diarrhoea, feeling or being sick. These symptoms are mild and disappear within a few days. 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.

4. Possible side effects

EFEXOR XR can have side effects.

Not all side effects reported for EFEXOR XR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking EFEXOR XR, please consult your health care provider for advice.

If any of the following happens, stop taking EFEXOR XR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swollen face or tongue, or shortness of breath or difficulty breathing.
- Severe skin rashes which may lead to blistering and peeling of the skin (this may be a serious allergic reaction).
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EFEXOR XR. You may need urgent medical attention or hospitalisation.

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

- Rapid or irregular heartbeat, flushing.
- Difficulty in breathing (dyspnoea).
- Inflammation of the mouth and throat, and a runny nose, which may be a sign of infection.
- Difficulty in urinating.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Change in appetite (decrease).

- Difficulty sleeping.
- Abnormal dreams.
- Nervousness.
- Reduced sex drive.
- Lack of orgasm.
- Dizziness.
- Drowsiness,
- Tremor (shaking).
- Strange feeling on the skin such as “pins and needles” or burning.
- Altered taste sensation.
- Blurred vision, dilation of the pupils.
- Increased blood pressure.
- Yawning.
- Feeling sick.
- Dry mouth.
- Constipation.
- Being sick (vomiting).
- Abdominal discomfort or stomach ache.
- Skin rash.
- Increased muscle tone (muscle spasm).
- Back pain.
- Trouble starting or maintaining a urine stream.
- Impotence.
- Change in sexual function e.g. abnormal ejaculation in men.
- Unusual tiredness or weakness.
- Pain.
- Chest pain.
- Weight loss or gain.
- Increased blood cholesterol.

Less frequent side effects

- Feeling high or overexcited (mania or hypomania).
- Hallucinations.
- Feeling separated (or detached) from the outside world.
- Lack of interest, enthusiasm or concern.
- Suicidal ideation and suicidal behaviours; cases of suicidal ideation and suicidal behaviours have been reported during venlafaxine therapy or early after treatment discontinuation.
- Feeling aggressive or having aggressive thoughts.
- Sudden spasm of the muscles.
- Seizure or fit.
- Vertigo.
- Problems with heart rhythm.
- Feeling dizzy or unsteady on when standing up due to a fall in blood pressure (especially if you are elderly).
- Discolouration of the skin resulting from bleeding underneath, typically caused by bruising.
- Increased sensitivity of your skin to sunlight.
- Feeling the need to go to the toilet more often than usual.

Other side effects

- Blood cell disorders where your red, white and platelet cell levels are affected.
- Excessive water intake (known as SIADH).
- Abnormal breast milk production.
- Decreased sodium in your body.
- Increased appetite.
- Confusion.
- Feeling separated (or detached) from oneself.
- Agitation,
- Clenching or grinding of teeth.
- Disorientation and confusion often accompanied by hallucination (delirium).
- Anxiety.

- Depression.
- Quick changes in mood where strong emotions or feelings may occur, such as uncontrollable laughing or crying, or heightened irritability or temper.
- Headache.
- Feeling of restlessness or if you feel unable to sit or stand still.
- Loss of balance and abnormal coordination.
- Involuntary movements of the muscles.
- A high temperature with rigid muscles, confusion or agitation, and sweating or if you experience jerky muscle movements which you cannot 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.
- Movement disorder in which a person's muscles contract uncontrollably (dystonia).
- Loss of memory.
- Numbness.
- Sleepiness.
- Abnormal thinking.
- Eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- Tinnitus (ringing in the ears).
- Abnormal heart rhythm that may be serious.
- Decreased blood pressure.
- Difficulty in breathing (interstitial lung disease and pulmonary eosinophilia).
- Diarrhoea, internal bleeding of the stomach or intestines, severe pain in the stomach radiating to the back that may mean you have inflammation of the pancreas, indigestion, belching, excess amount of gas in the stomach.
- Changes in blood levels of liver enzymes.
- Itchiness, yellow skin or eyes, dark urine, or flu-like symptoms, which are symptoms of inflammation of the liver (hepatitis).
- Sweating (including night sweats).

- Itching of the skin and hives.
- Abnormal hair loss.
- Severe skin reaction which may lead to blistering and peeling of the skin and is potentially life-threatening.
- Unexplained muscle pain, tenderness or weakness. This may be a sign of rhabdomyolysis.
- Sore muscles.
- Spasm of the jaw muscles, keeping the jaws tightly closed.
- Increased urinary frequency and feeling the need to go to the toilet more often than usual.
- Abnormal bleeding from the uterus or abnormally heavy bleeding at menstruation.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage) (see Pregnancy and breastfeeding).
- Chills.
- Bleeding from your mucosal surfaces.
- Increased bleeding 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of EFEXOR XR.

5. How to store EFEXOR XR

Store all medicines out of reach of children.

Store in a cool (at or below 25 °C), dry place.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or

sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EFEXOR XR contains

The name of your medicine is EFEXOR XR.

- The active substance 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.
- The content of the capsules is anhydrous methanol, ethylcellulose, hypromellose, methylene chloride and microcrystalline cellulose.
- The capsule shells contain gelatine, red iron oxide, talc, titanium dioxide, yellow iron oxide and red (75 mg) or white (150 mg) printing ink.

What EFEXOR XR looks like and contents of the pack

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.

EFEXOR XR 75 mg: Clear or opaque PVC/aluminium 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: Clear or opaque PVC/aluminium 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.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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BOTSWANA: S2

EFEXOR XR 75 mg – Reg. No.: BOT0300583

EFEXOR XR 150 mg – Reg. No.: BOT0300584

NAMIBIA: NS3

EFEXOR XR 75 mg – Reg. No.: 04/1.2/1124

EFEXOR XR 150 mg – Reg. No.: 04/1.2/1125