EFEXOR® -XR

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking EFEXOR-XR?

EFEXOR-XR contains the active ingredient venlafaxine hydrochloride. EFEXOR-XR is used in the treatment and prevention of relapse of depression. It is also used in the treatment of panic attacks and anxiety, including avoidance or fear of social situations.
For more information, see Section 1. Why am I taking EFEXOR-XR? in the full CMI.

2. What should I know before I take EFEXOR-XR?

Do not use if you have ever had an allergic reaction to venlafaxine or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I take EFEXOR-XR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EFEXOR-XR and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take EFEXOR-XR?

- Your doctor will tell you how many capsules you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.
- Swallow the capsules whole with a glass of water. Do not divide, crush, chew or dissolve the capsules in water.

More instructions can be found in Section 4. How do I take EFEXOR-XR? in the full CMI.

5. What should I know while taking EFEXOR-XR?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using EFEXOR-XR. • 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. • Tell your doctor immediately if you have any symptoms of serotonin syndrome, or if you have any thoughts about suicide or doing harm to yourself.
Things you should not do	• Do not suddenly stop taking this medicine or lower the dose if you have been taking it for some time.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how EFEXOR-XR affects you. • EFEXOR-XR capsules may make you feel drowsy.
Drinking alcohol	• Avoid drinking alcohol while you are taking EFEXOR-XR.
Looking after your medicine	• Store it in a cool dry place below 30°C away from moisture, heat or sunlight. • Keep it where children cannot reach it.

For more information, see Section 5. What should I know while taking EFEXOR-XR? in the full CMI.

6. Are there any side effects?

Speak to our doctor or pharmacist if you have nausea, vomiting, loss of appetite, diarrhoea, constipation, change in behaviour, feeling drowsy, headache, rapid heartbeat, sweating, hot flushes, rash, itchiness, weight change, blurred vision or dry mouth.
Call your doctor immediately if you have muscle tremors, abnormal facial movements, feeling of apathy, hallucinations, agitation, confusion, muscle weakness, numbness, shortness of breath, bleeding, bruising more easily than normal or sensitivity to sunlight.
Call your doctor immediately or go to Emergency at your nearest hospital if you have fits or seizures, signs of allergy, sudden fever with sweating, rapid heartbeat and muscle stiffness, palpitation, intense chest pain, dark or red urine, yellowing of skin or eyeballs, signs of infection, black sticky bowel motions, bloody diarrhoea, high fever, confusion and abrupt muscle contraction.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

EFEXOR® -XR

Active ingredient: *Venlafaxine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using EFEXOR-XR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EFEXOR-XR.**

Where to find information in this leaflet:

1. Why am I taking EFEXOR-XR?
2. What should I know before I take EFEXOR-XR?
3. What if I am taking other medicines?
4. How do I take EFEXOR-XR?
5. What should I know while taking EFEXOR-XR?
6. Are there any side effects?
7. Product details

1. Why am I taking EFEXOR-XR?

EFEXOR-XR contains the active ingredient venlafaxine hydrochloride. It belongs 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.

EFEXOR-XR is used in the treatment and prevention of relapse of depression. It is also used in the treatment of panic attacks and 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Use in Children

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.

2. What should I know before I take EFEXOR-XR?

Warnings

Do not use 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.**
- **you are allergic to venlafaxine, or any of the ingredients listed at the end of this leaflet.**
  Symptoms of an allergic reaction may include:
  - 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.

Always check the ingredients to make sure you can use this medicine.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor or pharmacist if you:

- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with 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 this medicine 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.

If you take EFEXOR-XR or similar anti-depressants mid to late in your pregnancy, you may develop a condition known as "pre-eclampsia", which is characterised by persistent high blood pressure during or after pregnancy. Symptoms of preeclampsia can include headaches,

abdominal pain, shortness of breath or burning behind the sternum, nausea and vomiting, confusion, heightened state of anxiety, and/or visual disturbances such as oversensitivity to light, blurred vision, or seeing flashing spots or auras.

If you take EFEXOR-XR or similar antidepressants in the last month of your pregnancy, you may experience heavy vaginal bleeding shortly after birth (postpartum haemorrhage).

Continuing treatment with EFEXOR-XR or similar antidepressants during pregnancy should be strictly as directed by your doctor. Symptoms of a relapse may occur if treatment is discontinued, even if major depression was previously under control.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

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 of the following medical conditions:

- A history of fits (seizures or convulsions)
- A personal history or family history of bipolar disorder
- A history of aggression
- A history of restlessness or difficulty sitting still
- Diabetes
- Blood pressure problems
- Glaucoma (increased pressure in the eye)
- A tendency to bleed more than normal or you are taking medicines to prevent blood clots
- Raised cholesterol levels or you are taking medicines to lower cholesterol
- Problems with your kidneys or liver
- Problems with your heart, especially conditions causing irregular heartbeats.

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

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 start taking EFEXOR-XR.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you take any other medicines, including:

- all prescription medicines
- medicines for weight loss
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

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 moclobemide, linezolid, 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
- Allow at least 7 days after stopping EFEXOR-XR before starting a MAOI.

  Taking this medicine with a MAOI, or within 7 days of taking a MAOI, may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

  The appropriate washout period is needed to prevent severe adverse reactions.
- Any other medications for depression, anxiety, obsessive-compulsive disorder or premenstrual dysphoric disorder, including St John's wort
- Medicines for treating mental disorders such as haloperidol, risperidone, lithium or clozapine
- Tramadol, fentanyl, tapentadol, pethidine and methadone used to treat strong pain
- Medicines used to treat Attention Deficit Hyperactivity Disorder (ADHD) such as dexamphetamine and Lisdexamphetamine
- Cimetidine for reflux and stomach ulcers
- Triptans used to treat migraine
- Amiodarone or quinidine used to treat irregular heartbeats.

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

- Metoprolol for high blood pressure or angina
- Medicines used to prevent blood clotting such as anti-coagulants and platelet inhibitors
- Indinavir for viral infections
- Antibiotics such as erythromycin and linezolid for bacterial infections
- Ketoconazole or fluconazole for fungal infections.

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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How do I take EFEXOR-XR?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many capsules you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Depression and Anxiety

The usual starting dose is 75 mg taken once daily. After 2 weeks, your doctor may increase the dose to 150 mg a day.

Panic attacks

The usual starting dose is 37.5 mg taken once daily for the first 4 to 7 days, then increased to 75 mg taken once daily.

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 your doctor may first do some blood tests or heart tests such as an electrocardiogram (ECG) before increasing your dose of 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.

When to take EFEXOR-XR

- **Take your medicine once daily with food, at approximately the same time each day.**
- This could be either in the morning or in the evening.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take EFEXOR-XR

- **Continue taking your medicine for as long as your doctor tells you.**
- 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.
- This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

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.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much EFEXOR-XR

If you think that you or anyone else may have taken too much EFEXOR-XR, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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
- Have a decreased blood sugar level.

Keep the telephone number for these places handy whilst taking any medications.

5. What should I know while taking EFEXOR-XR?

Things you should do

Visit your doctor regularly for a checkup so that your progress can be checked.

Your doctor may do some tests (such as an electrocardiogram (ECG) or blood tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Always discuss any questions you have about EFEXOR-XR capsules with your doctor.

If you are going to have surgery, tell your doctor that you are taking this medicine.

Some agents used to assist your doctor during surgery may interact with EFEXOR-XR leading to unwanted side effects.

If you are about to have any urine tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Take EFEXOR-XR capsules as your doctor has prescribed.

Keep enough EFEXOR-XR capsules to last weekends and holidays.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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) when treated 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.

Call your doctor straight away if you experience:

- 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
- Tremor, sweating, fast heart rate
- Muscle rigidity.

Symptoms of serotonin syndrome may include mental status changes (e.g. agitation, confusion, hallucinations, and coma), autonomic instability (e.g. excessive sweating, fast heart rate, and increased body temperature), neuromuscular aberrations (e.g. overactive reflexes, incoordination, tremor) and/or gastrointestinal symptoms (e.g. nausea, vomiting, and diarrhoea).

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

Warning signs of suicide

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.

All thoughts or talk about suicide or violence are serious.

- 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 you should not do

- **Do not suddenly stop taking this medicine or lower the dose if you have been taking it for some time.**
  If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.
  If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as:
  - 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.
- **Do not give this medicine to anyone else even if they have the same condition as you.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how EFEXOR-XR affects you.

EFEXOR-XR capsules may make you feel drowsy.

Some of the aforementioned symptoms may impair driving, or the operation of dangerous machinery. Avoid these activities if you experience these symptoms.

Things to be careful of

If you are feeling drowsy or are uncoordinated, be careful that you do not fall over.

EFEXOR-XR, like other medicines in this class, may increase your risk of bone fracture.

Drinking alcohol

Avoid drinking alcohol while you are taking EFEXOR-XR.

Alcohol can cause dizziness and lightheadedness. Alcohol may also worsen your condition.

Looking after your medicine

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

If you take the capsules out of the blister pack they may not keep well.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place below 30°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EFEXOR-XR.

All medicines can have side effects. Sometimes they are serious; often they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking this medicine, effects of your condition, or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of side effects.

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Stomach, bowel or urinary tract problems: • Nausea or vomiting • Loss of appetite • Diarrhoea • Constipation • Difficulty passing urine, passing urine more frequently, or urinary incontinence Changes in your behaviour: • Difficulty sleeping or abnormal dreams	**Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.**
• Paranoia • Aggression • Sexual function problems such as delayed ejaculation, problems with erection, decreased sex drive or difficulties achieving orgasm. Medicines like EFEXOR-XR (so called SNRIs) may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment. • Nervousness • Teeth grinding • Impaired coordination and balance Difficulty thinking or working because of: • Yawning • Feeling sedated or drowsy • Fainting or dizziness after standing up • Restlessness or difficulty sitting still • Headache • Rapid heartbeat • Heavy or irregular menstrual periods Others: • Sweating • Hot flushes • Rash • Hair loss • Itchiness • Weight loss • Weight gain • Flow of milk in women who are not breastfeeding • Blurred vision • Ringing in the ears • Altered taste • Dry mouth.	

Serious side effects

Serious side effects	What to do
• Muscle tremors, spasms, twitching, jerky movements or sustained muscle contractions • Abnormal facial movements such as tongue thrusting, repetitive chewing, jaw swinging, or grimacing • A feeling of apathy or not caring about things • Hallucinations	**Call your doctor straight away, if you notice any of these serious side effects.**

Serious side effects	What to do
• Agitation • Confusion • Unusually overactive • Changes in muscle tone, muscle weakness or fatigue • Numbness or pins and needles. • Problems with breathing, shortness of breath • Cough • Bleeding or bruising more easily than normal • Sensitivity to sunlight.	

More Serious side effects

More Serious side effects	What to do
• 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 heartbeat and muscle stiffness, which may lead to loss of consciousness (symptoms resembling neuroleptic malignant syndrome) • Palpitations, shortness of breath, intense chest pain, or irregular heartbeats • 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.	**Call your doctor straight away, or go to Accident and Emergency at your nearest hospital if you notice any of these more serious side effects.** These symptoms are usually rare but may be serious and need urgent medical attention.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects (for example, increase in blood pressure or blood cholesterol) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What EFEXOR-XR contains

Active ingredient (main ingredient)	Venlafaxine hydrochloride 37.5 mg, 75 mg or 150 mg per capsule
Other ingredients (inactive ingredients)	Iron oxide yellow Iron oxide red Microcrystalline cellulose Ethylcellulose Hypromellose Gelatin Purified talc Titanium dioxide Red ink Opacode S-1-15094/S-1-15095 (EFEXOR-XR 37.5 mg and 75 mg strengths) White ink TekPrint SB-0007P (EFEXOR-XR 150 mg only) Iron oxide black (EFEXOR-XR 37.5 mg only).

Do not take this medicine if you are allergic to any of these ingredients.

What EFEXOR-XR looks like

EFEXOR-XR 37.5 mg: hard gelatin capsule, grey cap and peach body with "W" on the cap and "37.5" on the body in red ink, containing white to off-white spheroids of about 1 mm in diameter (AUST R 99802).

EFEXOR-XR 75 mg: hard gelatin capsule, peach cap and body with "W" on the cap and "75" on the body in red ink, containing white to off white spheroids of about 1 mm diameter (AUST R 60858).

EFEXOR-XR 150 mg: hard gelatin capsule, dark orange cap and body with "W" on the cap and "150" on the body in white ink, containing white to off white spheroids of about 1 mm diameter (AUST R 60859).

Each blister pack contains 28 capsules.

Who distributes EFEXOR-XR

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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