

VENLEXOR XR

Venlafaxine hydrochloride modified release capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VENLEXOR-XR capsule.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What VENLEXOR-XR is used for

VENLEXOR-XR capsules contain an active ingredient called "venlafaxine hydrochloride".

This medicine is used in the treatment and prevention of relapse of depression and in the treatment of social phobia (social anxiety disorder).

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 brain to work.

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

Depression is longer lasting or more severe than the 'low moods' that everyone has from time to time. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, lose interest in usual activities, be unable to enjoy life, have poor appetite or over eat, have disturbed sleep, often waking up early, loss of sex drive, low energy and feel guilty over nothing.

Social phobia is a fear of being embarrassed, judged or evaluated negatively in social situations, which can result in substantial impairment in the person's social emotional, interpersonal and occupational life.

Depression and anxiety are treatable illnesses. Anxiety and tension associated with the normal stress of daily life usually does not require treatment with medicines.

There is no evidence that VENLEXOR-XR is addictive.

Ask your doctor if you have any questions about why VENLEXOR-XR has been prescribed for you.

Your doctor may have prescribed VENLEXOR-XR capsules for another purpose.

Before you take VENLEXOR-XR

When you must not take it

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

Some of the symptoms of an allergic reaction may include:

- Skin rash
- Itching or hives on the skin
- Swelling of the face, lips, tongue or other parts of the body
- Shortness of breath, wheezing or troubled breathing.

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

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

Do not take VENLEXOR-XR after the expiry date 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 take VENLEXOR-XR if the packaging is torn or show signs of tampering.

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

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

Before you start to take it

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

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

VENLEXOR-XR is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of using VENLEXOR-XR if you are pregnant.

One of these risks is that newborn babies whose mothers have been taking VENLEXOR-XR may have several problems soon after delivery, including breathing difficulties, high blood pressure, seizures and lack of oxygen in their blood.

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

VENLEXOR-XR passes into breast milk and there is a possibility that the breast-fed baby may be affected. For this reason, the use of VENLEXOR-XR is not recommended in breastfeeding 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
- Problems with your kidneys or liver
- Problems with your heart
- A tendency to bleed more than normal
- Raised cholesterol levels
- Blood pressure problems
- Glaucoma (increased pressure in the eye).

Your doctor may wish to do some heart tests such as an electrocardiogram (ECG) or blood tests during treatment with VENLEXOR-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 take VENLEXOR-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 John's Wort or tryptophan supplements.

Do not start to take any other medicine while you are taking VENLEXOR-XR, unless it is prescribed or approved by your doctor.

Some medicines and VENLEXOR-XR may interfere with each other. 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)
- Triptans (used to treat migraine)
- Cimetidine (used to treat reflux and stomach ulcers)
- Amiodarone or quinidine (used to treat irregular heart beats)
- Tramadol (a pain killer).

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 VENLEXOR-XR:

- Warfarin (used to prevent blood clotting)
- Indinavir (an antiviral)
- Medications for weight loss, including sibutramine
- Erythromycin and linezolid (used to treat infections)
- Ketoconazole or fluconazole (used as antifungal medicines)
- Metoprolol (used to treat high blood pressure or angina).

These medicines may be affected by VENLEXOR-XR or may affect how well it works. You may need different amounts of your medicines, 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 VENLEXOR-XR.

How to take VENLEXOR-XR

DO NOT DIVIDE, CRUSH, CHEW OR DISSOLVE.

VENLEXOR-XR capsules are to be swallowed whole. Do not divide, chew, crush or place the capsules in water.

Inside VENLEXOR-XR capsules are tablets that contain the venlafaxine active ingredient. As the medicine travels the length of your gastrointestinal tract, venlafaxine is slowly released.

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

The usual starting dose is 75mg taken once daily. If necessary, after two weeks, your doctor may increase your dose.

Do not change the dose unless your doctor tells you to.

If you have kidney or liver problems, you may need a lower dose of VENLEXOR-XR.

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

When to take it

VENLEXOR-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 VENLEXOR-XR.

Your doctor may have switched your treatment from Venlafaxine Hydrochloride tablets to VENLEXOR-XR capsules. If this happens, your doctor will normally prescribe a dose that is equivalent to your total daily dose of tablets. The dose of VENLEXOR-XR capsules should be taken only once daily.

If you forget to take it

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.

How long to take it for

The length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so don't be discouraged if you don't feel better right away.

Some of your symptoms may improve in 1 or 2 weeks but it can take up to another few weeks to feel any real improvement.

Even when you feel well, you will usually have to take VENLEXOR-XR for several months or even longer to make sure the benefits will last.

Discuss this with your doctor and don't stop taking VENLEXOR-XR until gaining your doctor's agreement.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much VENLEXOR-XR.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy. Take the pack of capsules with you to the doctor or hospital.

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

- Feel sleepy
- Vomit
- Have an increased heart rate or changes in heart rhythm
- Have a seizure (fit)
- Have breathing difficulties
- Become unconscious
- Have dilated pupils.

While you are taking VENLEXOR-XR

Things you must do

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

Take VENLEXOR-XR capsules as your doctor has prescribed.

Keep enough VENLEXOR-XR capsules to last over weekends and holidays.

You need a prescription from your doctor to get more VENLEXOR-XR capsules.

Watch carefully for signs that your depression or anxiety is getting worse, especially in the first few weeks of treatment.

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 VENLEXOR-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 you must not do

Do not stop taking VENLEXOR-XR or lower the dose suddenly, without first checking with your doctor.

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

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

- Headache
- Nausea and vomiting
- Dizziness
- Insomnia
- Nervousness
- Anxiety
- Confusion and agitation
- Diarrhoea
- Sweating
- Loss of appetite
- Impaired coordination and balance
- Tingling or numbness of the hands and feet
- Tremor
- Flu-like symptoms.

Slowly reducing the amount of VENLEXOR-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 take VENLEXOR-XR to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

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

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
- Abnormal facial movements such as tongue thrusting, repetitive chewing, jaw swinging, or grimacing
- Impaired coordination and balance

- 75 mg: AUST R 151885
- 150 mg: AUST R 151874

- 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, VENLEXOR-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
- Increased 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 or tongue, wheezing or difficulty breathing
- 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
- Symptoms of a high fever, agitation, confusion, trembling and abrupt contractions of muscles
- Signs of an infection such as mouth ulcers severe chills, fever and sore throat

- 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 VENLEXOR-XR

Storage

Keep your VENLEXOR-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 VENLEXOR-XR capsules in a cool dry place where the temperature stays below 25°C.

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

Heat and dampness can destroy some medicines.

Keep VENLEXOR-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

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.

Product description

What it looks like

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

- VENLEXOR XR 75mg capsules are presented as flesh opaque capsules.
- VENLEXOR XR 150mg capsules are presented as scarlet opaque capsules.
- VENLEXOR-XR 75 mg and 150 mg are available in blister packs of 28 capsules.

Ingredients

VENLEXOR XR capsules contain venlafaxine hydrochloride as the active ingredient.

VENLEXOR XR 75 mg and 150 mg capsules contain the following inactive ingredients:

- Hypromellose
- Sodium lauryl sulfate
- Magnesium stearate
- Ammonio methacrylate copolymer
- Basic butylated methacrylate copolymer
- Titanium dioxide (E171)
- Gelatin.

The 75mg capsules also contain red iron oxide (E172).

The 150mg capsules also contain Erythrosine (E127) and Indigo carmine (E132).

Supplier

www.ascentpharma.com.au