

VENLA RBX

Venlafaxine Modified Release Capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VENLA RBX (venlafaxine hydrochloride) modified release capsules.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking VENLA RBX against the benefits it is expected to have for you.

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

Keep this leaflet with this medicine.

You may need to read it again.

What VENLA RBX is used for

VENLA RBX contains the active ingredient venlafaxine (as hydrochloride).

VENLA RBX is used for the treatment and prevention of relapse of depression, and for 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.

VENLA RBX is not addictive.

Your doctor may have prescribed VENLA RBX capsules for another purpose. Ask your doctor if you have any questions about why VENLA RBX has been prescribed for you.

How does VENLA RBX work?

VENLA RBX 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. VENLA RBX increases the level of these two messengers. Experts think this is how it helps to restore your feeling of wellness.

It is available only with a doctor's prescription.

Before you take VENLA RBX

When you must not take it

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

Symptoms of an allergic reaction 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

Do not give VENLA RBX to children or adolescents under 18 years of age.

The safety and effectiveness of VENLA RBX in this age group have not been established.

Do not use VENLA RBX after the expiry date (EXP) 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 use VENLA RBX if the packaging is torn or shows signs of tampering.

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

Before you start to take VENLA RBX

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

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

VENLA RBX is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of using VENLA RBX if you are pregnant. One of these risks is that newborn babies whose mothers have been taking VENLA RBX in the last few months of pregnancy, may experience problems soon after delivery, including breathing difficulties, seizures and lack of oxygen in their blood.

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

Venlafaxine passes into breast milk and there is a possibility that the breast-fed baby may be affected. For this reason, the use of VENLA RBX is not recommended in breast-feeding 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
- Blood pressure problems

- Glaucoma (increased pressure in the eye)
- A tendency to bleed more than normal
- Raised cholesterol levels
- Problems with your kidneys or liver
- Problems with your heart

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

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 VENLA RBX.

Taking other medicines

Tell your doctor or pharmacist if you take any other medicines, including all prescription medicines, 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 VENLA RBX, unless it is prescribed or approved by your doctor.

Some medicines may interfere with VENLA RBX or VENLA RBX 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
- 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)
- Tramadol, fentanyl, tapentadol, pethidine, methadone and pentazocine (pain killers)
- Cimetidine (used to treat reflux and stomach ulcers)
- Triptans (used to treat migraine)
- Amiodarone or quinidine (used to treat irregular heart beats)

Your doctor may wish to do some heart tests such as an electrocardiogram (ECG) or blood tests if you are using any of these medicines whilst taking VENLA RBX:

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

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 or pharmacist has more information on medicines to be careful with or to avoid while taking VENLA RBX.

How to take VENLA RBX

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. If necessary, after two weeks, your doctor may increase your dose.

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

How to take it

Swallow the capsules whole with a glass of water or other non-alcoholic liquid. Do not divide, crush, chew or place the capsules in water.

Inside VENLA RBX 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.

When to take it

VENLA RBX 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. Taking it at the same time each day will have the best effect. It will also help you to remember when to take it.

Avoid drinking alcohol while you are using VENLA RBX.

How long to take VENLA RBX

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 VENLA RBX time to work.

Even when you feel well again, you may need to keep taking VENLA RBX for several months to make sure the benefits last. Discuss this with your doctor and don't stop taking VENLA RBX until gaining your doctor's agreement.

If you forget to take VENLA RBX

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.

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.

If you take too much (overdose)

It is important that you do not take more VENLA RBX capsules than your doctor has prescribed. If you do take more than you have been prescribed, contact your doctor immediately for advice.

If anyone accidentally swallows any VENLA RBX capsules, call your nearest Poisons Information Centre (tel. 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. Keep the telephone number for these places handy whilst taking any medications.

If you take too many VENLA RBX 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

While you are using VENLA RBX

Things you must do

Visit your doctor regularly for a check up so that your progress can be checked. Always discuss any questions you have about VENLA RBX with your doctor.

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.

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 VENLA RBX 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 VENLA RBX as your doctor has prescribed.

Keep enough VENLA RBX 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. You need a prescription from your doctor to get more VENLA RBX capsules.

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

Watch carefully for signs that your depression 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) during treatment with venlafaxine, 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 usual 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 to be careful of

VENLA RBX may make you feel drowsy. **Be careful driving or operating dangerous machinery until you know how it affects you.**

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

VENLA RBX, like other medicines in this class, may increase your risk of bone fracture.

Things you must not do

Do not suddenly stop taking VENLA RBX if you have been taking it for some time.

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

Side effects from stopping treatment suddenly with VENLA RBX may include:

- 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 VENLA RBX 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 give this medicine to anyone else even if they have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VENLA RBX.

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.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

Stomach, bowel or urinary tract problems such as:

- Nausea or vomiting
- Loss of appetite
- Diarrhoea
- Constipation

- Difficulty passing urine, passing urine more frequently, or urinary incontinence

Changes in your behaviour such as:

- Difficulty sleeping or abnormal dreams
- Paranoia
- Sexual function problems such as delayed ejaculation, problems with erection, decreased sex drive or difficulties achieving orgasm
- 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 heart beat
- Problems with breathing
- Heavy or irregular menstrual periods

Changes in your appearance such as:

- Sweating
- Hot flushes
- Rash
- Hair loss
- Itchiness
- Weight loss or weight gain
- Flow of milk in women who are not breast-feeding

In some people, VENLA RBX may lead to changes in the way your blood clots.

Changes in your sight, hearing, taste or touch such as:

- Blurred vision
- Ringing in the ears
- Altered taste
- Dry mouth

Tell your doctor immediately if you notice any of the following:

- 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
- Agitation
- Confusion
- Unusually overactive
- Changes in muscle tone, muscle weakness or fatigue
- Numbness or pins and needles
- Problems with breathing, shortness of breath
- Bleeding or bruising more easily than normal
- Sensitivity to sunlight

Tell your doctor immediately, or go to Accident and Emergency at 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 or swallowing
- 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
- 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

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.

Other side effects not listed above may also occur in some patients. 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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

After using it

Storage

Keep your VENLA RBX 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 VENLA RBX in a cool dry place where the temperature stays below 25°C.

Do not store VENLA RBX or any other medicine in the bathroom or near a sink. Do not leave VENLA RBX capsules in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep VENLA RBX 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

Return any unused medicine to your pharmacist.

Product description

What it looks like

VENLA RBX 75 and 150 mg capsules are available in blister packs of 28 capsules.

- VENLA RBX 75 mg capsules are peach cap and body with thick and thin radial circular bands on the cap and body in red ink.
- VENLA RBX 150 mg capsules are dark orange cap and body with thick and thin radial circular bands on the cap and body in white ink.

Ingredients

Active ingredient

- VENLA RBX 75 mg capsule contains 75 mg of venlafaxine (as hydrochloride)
- VENLA RBX 150 mg capsule contains 150 mg of venlafaxine (as hydrochloride)

Inactive ingredients

- microcrystalline cellulose
- povidone
- purified talc
- colloidal anhydrous silica
- magnesium stearate
- ethylcellulose
- copovidone
- gelatin
- titanium dioxide
- iron oxide black, iron oxide red and TekPrint SB-1033 Red Ink (proprietary ingredient # 106948)(75 mg capsule only)

- Brilliant Blue FCF, Allura Red AC, Sunset Yellow FCF and TekPrint SB-0007P White Ink (proprietary ingredient # 2216) (150 mg capsule only)

VENLA RBX capsules do not contain gluten, lactose or sucrose.

Australian Registration Nos.

- VENLA RBX 75 mg capsules: AUST R 210374
- VENLA RBX 150 mg capsules: AUST R 210375

Sponsor

VENLA RBX capsules are supplied in Australia by:

Ranbaxy Australia Pty. Ltd.

9-13 Waterloo Road
Macquarie Park NSW 2113
Australia

This leaflet was prepared in August 2013.