

# VENLA MR CAPSULES

Venlafaxine hydrochloride (37.5 mg, 75 mg, 150 mg)

## What is in this leaflet

1. What **VENLA MR CAPSULES** is used for
2. How **VENLA MR CAPSULES** works
3. Before you use **VENLA MR CAPSULES**
4. How to use **VENLA MR CAPSULES**
5. While you are using **VENLA MR CAPSULES**
6. Side effects
7. Storage and disposal of **VENLA MR CAPSULES**
8. Product description
9. Manufacturer and Product registration holder
10. Date of revision

## What **VENLA MR CAPSULES** is used for

**VENLA MR CAPSULES** is used in the treatment and prevention of relapse of depression.

It is also used in the treatment of generalised anxiety disorder (generally feeling very anxious or nervous, even when there is little or no reason to worry about them) and social anxiety disorder/social phobia (fear or avoidance of social situations).

## How **VENLA MR CAPSULES** works

**VENLA MR CAPSULES** contains the active substance venlafaxine hydrochloride which is an antidepressant that belongs to a group called selective serotonin and noradrenaline reuptake inhibitor (SNRI).

It is thought that people who are depressed have lower levels of serotonin and noradrenaline in the brain. It is not fully understood how antidepressants work, but they may help by increasing the levels of serotonin and noradrenaline in the brain.

## Before you use **VENLA MR CAPSULES**

– When you must not use it

## Do not take **VENLA MR CAPSULES** if you

- have an allergy to venlafaxine or any of the ingredients of this medicine (see **Product description** at the end of this leaflet)
- are also taking or have taken any time within the last 14 days any medicines known as monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Also, you must wait at least 7 days after you stop taking this medicine before you take any MAOI
- suffer from heart disease or have high blood pressure (hypertension) which is not being lowered by treatment

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

The expiry date refers to the last day of that month. If it has expired or is damaged, return it to your pharmacist for disposal.

– Before you start to use it

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

## Tell your doctor if you:

- have a history of epilepsy, fits or seizures
- have personal or family history of mania (feeling over-excited or euphoric) or bipolar disorder (extreme mood swings ranging from episodes of depression to mania).
- have a history of aggressive behaviour
- suffer from, or have a history of glaucoma (increased pressure in the eye)
- have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders)
- have low sodium levels in your blood (hyponatraemia)

- have high blood pressure
- have heart problems

## Pregnancy and lactation

Tell your doctor if you are currently pregnant, breast-feeding, or trying to get pregnant. Do not take **VENLA MR CAPSULES** until you and your doctor have discussed the risks and benefits involved.

– Taking other medicines

## Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **VENLA MR CAPSULES** may interfere with each other. These include:

- Monoamine oxidase inhibitors (MAOIs) such as moclobemide [see When you must not use it]
- Medicines used for treating migraine headaches i.e. Triptans (e.g. sumatriptan, rizatriptan)
- Medicines used to treat depression:
  - SNRI (e.g. desvenlafaxine, duloxetine),
  - SSRIs (e.g. citalopram, escitalopram, fluoxetine, sertraline),
  - tricyclics (e.g. amitriptyline, clomipramine),
  - medicines containing lithium
- An antibiotic linezolid (used to treat infections)
- Medicines containing phentermine (used for weight loss)
- Medicines containing tramadol (a pain-killer)
- Products containing St. John's Wort (also called *Hypericum perforatum*, a natural or herbal remedy used to treat mild depression)
- Products containing tryptophan (used for problems such as sleep and depression).
- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Haloperidol (to treat psychiatric conditions)
- Clozapine (used as a sedative and in the treatment of schizophrenia [a

severe brain disorder in which people interpret reality abnormally])

- Warfarin, NSAIDs, aspirin, or other medicines that affect coagulation
- Electroconvulsive therapy (usually used in severe depression)
- Indinavir, for viral infections
- Cimetidine for reflux and stomach ulcers
- Diuretics, or water pills

Ask your doctor or pharmacist if you are not sure whether you are taking any of these medicines. You may need different amounts of your medicines or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

### How to use VENLA MR CAPSULES

#### – How much to use

**The use of this medicine is not recommended in children and adolescents under 18 years of age.**

**Follow all directions given to you by your doctor or pharmacist carefully.** They may differ from the information contained in this leaflet

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.

The usual recommended starting dose is 75 mg per day. The dose can be raised by your doctor gradually, and if needed, even up to a maximum dose of 225 mg daily for depression.

#### ***Liver or kidney problems:***

If you have kidney or liver problems, you may need a lower dose of **VENLA MR CAPSULES**.

#### ***Elderly patients:***

Your doctor may start with a lowest dose, particularly if you have kidney problems.

#### – When to use it

Swallow the capsules whole with a glass of water.

Do not divide, crush, chew or dissolve the capsules in water.

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.

Avoid drinking alcohol while you are taking **VENLA MR CAPSULES**.

#### – How long to use it

The duration of treatment may vary depending upon your condition and severity of illness. Continue taking your medicine for as long as your doctor tells you.

#### – If you forget to use it

If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the missed dose and take only a single dose as usual.

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

#### – If you use too much (overdose)

**Immediately telephone your doctor or the National Poison Centre for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much VENLA MR CAPSULES.** Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The symptoms of a possible overdose may include a rapid heartbeat, changes in level of alertness (ranging from sleepiness to coma), blurred vision, seizures or fits, and vomiting.

**While you are using VENLA MR CAPSULES**

#### – Things you must do

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

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

**Tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding.**

#### – Things you must not do

Do not stop taking venlafaxine without talking to your doctor. As sudden withdrawal of this medicine may lead to loss of appetite, agitation, anxiety, loose stool, dizziness, confusion, headache, lack of sleep, nausea, nervousness, tingling or shock-like electrical sensations, sweating, sleepiness, vomiting, vertigo and shaking.

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

**Do not use VENLA MR CAPSULES to treat any other complaints unless your doctor says to.**

#### – Things to be careful of

Be careful driving or operating dangerous machinery until you know how it affects you.

**VENLA MR CAPSULES** may make you feel drowsy.

*Thoughts of suicide and worsening of your depression or anxiety disorder.*

If you are depressed and/or have anxiety disorder 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 and/ or if you are young adult.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital right away.

### Side Effects

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

Tell your doctor as soon as possible if you do not feel well while you are taking **VENLA MR CAPSULES**. Do not be alarmed by the following lists of side effects. You may not experience any of them.

**Serious side effects**

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

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- severe skin reaction with symptoms such as painful red areas, blisters, or peeling of layers of skin.
- tiredness, headache, being short of breath when exercising, dizziness and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nosebleeds
- high blood pressure, abnormal heart rhythm, fast or irregular heartbeats
- fainting, fits
- yellowing of the skin or eyeballs, fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements
- shortness of breath
- temporary paralysis or weakness of muscles
- severe upper stomach pain

**Other side effects**

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

- constipation, nausea, loss of appetite, appetite decreased, loose stools, indigestion, vomiting, stomach pain, dry mouth
- unusual weakness, chills, fever, weight gain or weight loss, sweating headache, dizziness, sleeplessness, nervousness, drowsiness, yawning
- abnormal dreams, agitation, feeling anxious, confusion
- unusual muscle stiffness causing poor control of movement; tingling or numbness of the hands or feet
- joint pain, muscle pain
- frequent need to urinate
- sexual function problems such as

delayed ejaculation, problems, with erection, decreased sex drive or difficulties achieving orgasm (peak of the sexual excitement)

- menstrual cycle disorders
- abnormal vision, dilated pupils
- ringing in the ears

**Laboratory Abnormalities**

- increase in cholesterol levels, liver enzymes
- decrease in sodium levels
- prolonged bleeding time
- abnormal blood cell counts
- ECG (electrocardiogram) changes

**Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.**

**You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)**

**Storage and Disposal of VENLA MR CAPSULES**

– **Storage**

Keep **VENLA MR CAPSULES** where children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Keep **VENLA MR CAPSULES** in a cool, dry place where the temperature stays below 25°C. Heat and dampness can destroy some medicines.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Keep **VENLA MR CAPSULES** in the original blister pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

– **Disposal**

If your doctor tells you to stop taking **VENLA MR CAPSULES**, or the tablets have passed their expiry date,

ask your pharmacist what to do with any left over.

**Product description**

– **What VENLA MR CAPSULES looks like**

**VENLA MR CAPSULES** are modified-release capsules.

**VENLA MR CAPSULES 37.5 MG**  
Size ‘2’ hard gelatin capsule with Grey opaque cap and pink body imprinted with RVn on the cap and 37.5 on body containing white to off white spheroids

**VENLA MR CAPSULES 75 MG**  
Size ‘1’ hard gelatin capsule with Pink opaque cap and body imprinted with RVn on the cap and 75 on body containing white to off white spheroids

**VENLA MR CAPSULES 150 MG**  
Size ‘0’ hard gelatin capsule with Caramel opaque cap and body imprinted with RVn on the cap and 150 on body containing white to off white spheroids.

– **Ingredients**

– Active ingredient  
Venlafaxine hydrochloride equivalent to venlafaxine

– Inactive ingredients  
**VENLA MR CAPSULES contains:**  
purified water, talc, isopropyl alcohol, ethylcellulose, microcrystalline cellulose, triacetin, dichloromethane, hypromellose, povidone

– **MAL numbers:**

**VENLA MR CAPSULES 37.5 MG:**  
MAL20112146A

**VENLA MR CAPSULES 75 MG:**  
MAL20112148A

**VENLA MR CAPSULES 150 MG:**  
MAL20112147A

**Manufacturer**

**RANBAXY LABORATORIES LIMITED,**  
Paonta Sahib, Dist. Sirmour Himachal Pradesh – 173 025, India

**Product Registration Holder**

**RANBAXY (Malaysia) SDN. BHD.**  
Lot 23, Bakar Arang Industrial Estate,  
08000 Sungai Petani, Kedah, Malaysia.

**Date of Revision**

25/09/2015

**Serial Number**

BPFK(R4/1)150715/00197