VENXOR TABLET

Venlafaxine (75 mg)

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What Venxor is used for

Venxor is used for the treatment of depression and for prevention of recurrence depressive episodes.

How Venxor works

Venxor is an antidepressant that belongs to a group called serotonin and norepinephrine reuptake inhibitors (SNRIs). It is thought that people who are depressed and/or anxious have lower levels of brain chemicals known as serotonin and noradrenaline. 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 Venxor

- When you must not use it

Do not use:

- if you are allergic to venlafaxine or any other ingredients contained in this medicine as listed at the end of this leaflet.
- if you currently are being treated with other medicines known as monoamine oxidase inhibitors (MAOIs) (used in the treatment of depression or Parkinson's disease, including furazolidone, procarbazine, and selegiline). Venxor should not be used within 14 days of discontinuing MAOIs treatment.

Concurrent use of MAOIs with venlafaxine may increase the risk of developing serotonin syndrome (a potentially life-threatening condition associated with a combination of symptoms, such as confusion, agitation, restlessness, diarrhoea, nausea, vomiting, severe convulsions, or severely elevated blood pressure).

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

- Before you start to use it

Tell your doctor if you have allergies to venlafaxine or any ingredients contained in this medicine.

Take special care with Venxor

- If you have reduced kidney or liver function
- If you have a history of heart disease
- If you have a history of fits
- If you suffer from diabetes
- If you suffer from low or high blood pressure
- If you have difficulty in passing water
- If you suffer from mania (feeling high or very excited) or the opposite (hypomania).

<u>Use in children and adolescents</u> under the age of 18 years:

Venxor should normally not be used for children and adolescents under 18 years.

Pregnancy and lactation

Do not use Venxor if you are pregnant, trying to get pregnant or think you may be pregnant without discussing with your doctor first.

Do not use Venxor if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines,

including any that you buy without a prescription from pharmacy, supermarket or health food shop.

Your treatment with Venxor can be affected by other medicinal products. This applies for:

- MAOIs (See *When you must not use it*)
- Medicine to make your blood thinner (e.g. warfarin)
- Medicine against too much acid in the stomach (e.g. cimetidine)
- Medicine against migraine (a recurrent, throbbing headache, usually affecting only one side of the head) (e.g. sumatriptan)
- Medicine against seizures (e.g. clozapine)
- Medicine to treat depression (e.g. citalopram, fluoxetine, paroxetine, sertraline, lithium, diazepam and moclobemid)
- If you are taking medication containing haloperidol
- If you have electroconvulsive therapy (ECT) (usually used in severe depression)

How to use Venxor

Always use the medicine exactly as your doctor or pharmacist has told you. Read the direction labels carefully. If you have any concerns about how to use this medicine, talk to your doctor or pharmacist.

- How much to use

Your doctor will advise you how much to use each day, and for how long you will need to use.

Adults:

The usual dosage is 75 mg/day in two or three divided dose taken with food. If necessary your doctor may increase your dosage to a maximum of 375mg/day, generally administered in three divided doses.

Children and adolescents:

Not recommended in children and adolescents under the age of 18 years.

Patients with reduced liver-and kidney function:

If you suffer from either of these conditions, it is necessary to reduce/adjust the dosage. Follow your doctor's prescription.

- When to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

- How long to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

- If you forget to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist. Use the missed dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not use a double dose to make up for the dose that you missed. This may increase the chance of you getting unwanted side effects.

- If you use too much (overdose)

Immediately call your doctor or go to the emergency department at your nearest hospital if you or anyone else has taken a large amount of this medication.

Symptoms of an overdose include disturbance in heart rhythm, fast or slow pulse, reduced blood pressure, agitation and unconsciousness (from sleepiness to coma). Treatment of overdose is essentially symptomatic and supportive.

While you are using Venxor

- Things you must do

Use the medication exactly as your doctor prescribed.

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

Tell your doctor or pharmacist what other prescription and non-prescription medicines that you are taking or are about to start taking.

Tell all the doctors, dentists and pharmacists treating you that you are using Venxor.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not give Venxor to anyone else, even if their symptoms seem similar to yours.

Do not use your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine or lower the dosage without checking with your doctor. Your doctor may want you to gradually reduce the amount of Venxor you are taking before stopping completely.

- Things to be careful

If irritation, sensitisation or allergic reaction occurs, stop using it and ask your doctor.

If you are pregnant, trying to get pregnant or are breast-feeding, you should not use this medicine without first discussing it with your doctor.

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

Like all medicines, Venxor can cause side effects, although not everybody gets them.

Venxor is usually well tolerated. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Common:

- nausea
- vomiting
- insomnia (difficulty falling asleep)
- dry mouth
- headache
- hypertension (elevated blood pressure)
- dizziness
- constipation
- sweating
- nervousness
- vision disturbances (such as blurred vision)
- sexual dysfunction

Rare:

- edema (swelling caused by excess fluid trapped in the body's tissues)
- itching
- skin rash
- mania or hypomania
- menstrual changes
- seizures
- urinary effects (such as difficulty in passing urine)

Other side effects not listed above may occur in some patients. Ask your doctor or pharmacist to answer any questions you may have.

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

(Consumers→Reporting).

Storage and Disposal of Venxor

- Storage

Keep all medicines out of the sight and reach of children.

Do not use this medicine after the expiry date stamped on the pack.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Round, peach mottled uncoated tablet, bevel-edged, flat faces, "HOVID" embossed on one face and scored on the other.

- Ingredients

- Active ingredients
 Each tablet contain Venlafaxine
 Hydrochloride 84.9mg equivalent to
 Venlafaxine 75mg.
- Inactive ingredients
 - Starlac
 - Polyvinylpolypyrrolidone (Polyplasdone XL)
 - Iron Oxide Red
 - Iron Oxide Yellow
 - Collodial Silicon Dioxide
 - Stearic Acid
 - Magnesium Stearate

MAL Number(s)

MAL10100137A

Manufacturer

HOVID Bhd.

Lot 56442, 7 ½ Miles, Jalan Ipoh/ Chemor, 31200 Chemor, Malaysia.

Product Registration Holder

HOVID Bhd.

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