

Venlafaxine Extended Release Capsules (37.5 mg, 75 mg & 150 mg)

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What BINOVEN-ER is used for?

BINOVEN-ER is used in the treatment and prevention of relapse of depression.

It is also used in the treatment of generalized 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 BINOVEN-ER works

BINOVEN-ER 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 BINOVEN-ER

- When you must not use it?

Do not take BINOVEN-ER Capsule if;

- If you are allergic to venlafaxine or any of the other ingredients of this medicine.
- If you are also taking, or have taken within the last 14 days, any medicines known as irreversible monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking an irreversible MAOI together with BINOVEN-ER, can cause serious or even life-threatening side effects.

Also, you must wait at least 7 days after you stop taking BINOVEN-ER before you take any MAOI (see also the section entitled "medicines and BINOVEN-ER" and the information in that section about 'Serotonin Syndrome').

- Before you start use it

Consult your doctor or pharmacist if;

- If you use other medicines that taken together with BINOVEN-ER could increase the risk of developing serotonin syndrome (see the section "medicines and BINOVEN-ER").
- If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- If you have a history of high blood pressure.
- If you have a history of heart problems.
- If you have a history of fits (seizures).
- If you have a history of low sodium levels in your blood (hyponatraemia).
- If you have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders), or if you are taking other medicines that may increase the risk of bleeding e.g., warfarin (used to prevent blood clots).
- If you have a history of, or if someone in your family has had, mania or bipolar disorder (feeling over-excited or euphoric).
- If you have a history of aggressive behavior

- Taking other medicines

Do not start or stop taking any medicines, including those bought without a prescription, natural and herbal remedies, before checking with your doctor or pharmacist.

• Monoamine oxidase inhibitors which are used to treat depression or Parkinson's disease **must not be taken with BINOVEN-ER**. Tell your doctor if you have taken these medicines within the last 14 days. (MAOIs: see **the** section "What you need to know before you take BINOVEN-ER").

• Serotonin syndrome:

A potentially life-threatening condition or Neuroleptic Malignant Syndrome (NMS)-like reactions may occur with

venlafaxine treatment, particularly when taken with other medicines.

Examples of these medicines include:

- Triptans (used for migraine).
- Other medicines to treat depression, for instance SNRIs, SSRIs, tricyclics, or medicines containing lithium.
- Medicines containing linezolid, an antibiotic (used to treat infections).
- Medicines containing moclobemide, a MAOI (used to treat depression).
- Medicines containing sibutramine (used for weight loss).
- Medicines containing tramadol, fentanyl, tapentadol, pethidine, or pentazocine (used to treat severe pain).
- Medicines containing dextromethorphan (used to treat coughing).
- Medicines containing methadone (used to treat opioid drug addiction or severe pain).
- Medicines containing methylene blue (used to treat high levels of methaemoglobin in the blood).
- 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).
- Antipsychotics (used to treat a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, unclear reasoning and becoming withdrawn).

How to use BINOVEN-ER Capsule?

- How much to use BINOVEN-ER

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual recommended starting dose for treatment of depression, generalized anxiety disorder and social anxiety disorder 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.

If you are being treated for panic disorder, your doctor will start with a lower dose (37.5 mg) and then increase the dose gradually. The maximum dose for generalized anxiety disorder, social anxiety disorder and panic disorder is 225 mg/day.

Take BINOVEN-ER at approximately the same time each day, either in the morning or in the evening. Capsules must be swallowed whole with fluid and not opened, crushed, chewed or dissolved. BINOVEN-ER should be taken with food.

If you have liver or kidney problems, talk to your doctor, since your dose of this medicine may need to be different.

Do not stop taking this medicine without talking to your doctor (see the section "If you stop taking BINOVEN-ER").

- How long to use BINOVEN –ER

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 BINOVEN-ER

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 more than the daily amount of BINOVEN-ER that has been prescribed for you in one day.

- If you use too much BINOVEN-ER (overdose)

If you accidentally take too many BINOVEN-ER, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine pack with you so that people can see what you have taken.

Recommended treatment

General supportive and symptomatic measures are recommended; cardiac rhythm and vital signs must be monitored. When there is a risk of aspiration, induction of emesis is not recommended. Gastric lavage may be indicated if performed soon after ingestion or in symptomatic patients.

Administration of activated charcoal may also limit absorption of the active substance. Forced diuresis, dialysis, hemoperfusion and exchange transfusion are unlikely to be of benefit. No specific antidotes for venlafaxine are known.

While you are using BINOVEN –ER

- Things you must do

- Always tell your doctor or pharmacist about all the medicines you are taking.
- If you are going to have a general anesthetic, tell the doctor or dentist in charge that you are taking BINOVEN -ER.
- If you are diabetic, take particular care with your blood sugar control since BINOVEN -ER may make you less aware of low blood sugar levels.
- The doctor will want to keep an eye on your heart function while you are taking BINOVEN -ER.

You might also need regular eye examinations.

- Things you must not do

- If you feel dizzy or sleepy, or if you have problems with your eyes when you start to take these Capsule, do not drive or use any tools or machines until you know how this medicine affects you.

- Things to be careful of

- Be careful when drinking alcohol, it may affect you more than usual.

Side effects

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BINOVEN-ER 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 BINOVEN-ER. Do not be alarmed by the following lists of side effects. You may not experience any of them.

- 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, feeling calm and sleepy (sedate).
- 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 visiting the website nppra.moh.gov.my

(Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of BINOVEN-ER

Do not store above 30°C.

Do not take BINOVEN-ER capsule after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking the capsule, please take any unused capsule back to your pharmacist to be destroyed.

Do not throw them away with your normal household water or waste. This will help to protect the environment.

Product Description

- What it looks like?

Venlafaxine Extended Release Capsules 37.5 mg:

White to off white spherical to oval pellets filled in Empty hard gelatin capsule shell (size '3') of Opaque Grey color cap and Opaque Peach color body imprinted with "E" on cap and "73" on the body with edible black ink.

Venlafaxine Extended Release Capsules 75 mg:

White to off white spherical to oval pellets filled in Empty hard gelatin capsule shell (size '1') of Opaque Peach color cap and Opaque Peach color body imprinted with "E" on cap and "74" on the body with edible black ink.

Venlafaxine Extended Release Capsules 150 mg:

White to off white spherical to oval pellets filled in Empty hard gelatin capsule shell (size '0') of Opaque Dark Orange color cap and Opaque Dark Orange color body imprinted with "E"

on cap and "89" on the body with edible black ink.

- Ingredients

- *Active ingredient*

Venlafaxine Hydrochloride

- *Inactive ingredients*

Sugar Spheres, Hypromellose, Talc, Purified Water, Ethyl Cellulose, Methanol, Methylene Chloride,

- *MAL number:*

BINOVEN-ER

(Venlafaxine Extended Release Capsules 37.5 mg)

MAL18106142AZ

BINOVEN-ER

(Venlafaxine Extended Release Capsules 75 mg)

MAL18106143AZ

BINOVEN-ER

(Venlafaxine Extended Release Capsules 150 mg)

MAL18106144AZ

Manufacturer

Aurobindo Pharma Ltd,
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Hyderabad, 500090, India.

Product Registration Holder in Malaysia

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03/11/2023

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