

VENLIFT ER CAPSULE

Venlafaxine Hydrochloride (37.5mg, 75mg & 150mg)

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What VENLIFT ER is used for

VENLIFT ER are used in treatment for:

- Adults with depression including depression with associated anxiety, in hospitalized patients.
- Anxiety or Generalized Anxiety Disorder (GAD), including long term treatment.
- Prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes.
- Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV which are characterized by a significant amount of fear in one or more social situations, causing considerable distress and impaired ability to function in at least some parts of daily life.
- Panic disorder, including prevention of relapse.

How VENLIFT ER works

VENLIFT ER is an antidepressant that belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). This group of medicines is used to treat depression and other conditions such as anxiety disorders help by increasing the levels of serotonin

and noradrenaline in the brain. It is thought that people who are depressed and/or anxious have lower levels of serotonin and noradrenaline in the brain.

Before you use VENLIFT ER

- When you must not use it

Do not take VENLIFT ER:

- If you are allergic to venlafaxine or any of the other ingredients of VENLIFT ER.
- If you are also taking or have taken anytime 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 other medicines, including VENLIFT ER, can cause serious or even life-threatening side effects. Also, you must wait at least 7 days after you stop taking VENLIFT ER before you take any MAOI.

Pregnancy and lactation

Do not take VENLIFT ER if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking VENLIFT ER, stop taking it immediately and contact your doctor.

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

- Before you start to use it

Talk to your doctor or pharmacist before taking VENLIFT ER for below conditions:

- If you use other medicines that taken together with VENLIFT ER could increase the risk of developing serotonin syndrome
- 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 been told you have an abnormal heart rhythm.
- 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 behaviour.
- If you take VENLIFT ER near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor should be aware that you are taking VENLIFT ER so they can advise you.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor should decide whether you can take VENLIFT ER with other medicines. Do not start 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

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VENLIFT ER. Tell your doctor if you have taken these medicines within the last 14 days.

- Serotonin syndrome: A potentially life-threatening condition or Neuroleptic Malignant Syndrome (NMS)-like reactions 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, Ketoconazole (an antifungal medicine).
- Haloperidol or risperidone (to treat psychiatric conditions).
- Metoprolol (use to treat high blood pressure and heart problems).
- Anti-viral medicine like indinavir used for HIV.
- Warfarin medicine used to prevent the formation of blood clots in the blood vessels.
- Cimetidine-medicine used for heart burn.
- Diazepam-medicine used to relieve anxiety

How to use VENLIFT ER

- How much to use

Always take this medicine exactly as your doctor has told you. You should 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.

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, major depressive disorder, social anxiety disorder and panic disorder is 225 mg/day.

- When to use it

Take VENLIFT 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.

VENLIFT 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 “*Things you must not do*”).

- How long to use it

Ask your doctor or pharmacist how long you can take it. Do not initiate or stop the treatment without consulting your doctor.

Stopping your treatment with VENLIFT ER may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

- 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. Do not take more than the daily amount of VENLIFT ER that has been prescribed for you in one day.

- If you use too much (overdose)

Call your doctor or pharmacist immediately if you take more of this medicine than the amount prescribed

by your doctor. 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 it

- Things you must do

- Take VENLIFT ER at about the same time each day.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking VENLIFT ER.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give VENLIFT ER to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the capsules make you feel dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Do not consume alcohol while you are on these medications.

Medicines like VENLIFT ER (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.

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Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

- Asthenia or fatigue.
- Vasodilatation (mostly hot flashes/flushes).
- Hypertension (high blood pressure).
- Appetite decreased.
- Constipation.
- Nausea.
- Vomiting.
- Serum cholesterol increased (particularly with prolonged administration and possibly with higher doses).
- Weight loss.
- Abnormal dreams.
- Decreased libido.
- Dizziness.
- Dry mouth.
- Increased muscle tonus.
- Insomnia (difficult to sleep).
- Nervousness.
- Paresthesia (prickling or burning sensation in feet, legs, arms or hands).
- Sedation.
- Tremor.
- Yawning.
- Sweating (including night sweats).
- Abnormality of accommodation.
- Mydriasis (dilation of the pupil of the eye).
- Visual disturbance.
- Abnormal ejaculation / orgasm (males).
- Anorgasmia (inability to reach orgasm).
- Erectile dysfunction.
- Urination impaired (mostly hesitancy).
- In Children:
 - Abdominal pain.

- Agitation.
- Dyspepsia (indigestion).
- Ecchymosis (a discoloration of the skin resulting from bleeding underneath, typically caused by bruising).
- Epistaxis (nosebleed).
- Myalgia (muscle pain).
- Decreased appetite.
- Weight loss.
- High blood pressure.
- Increased serum cholesterol.
- Major depressive disorder.
- Suicide-related adverse events such as suicidal ideation and self-harm.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers

➡ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of VENLIFT ER

- Storage
 - Store below 30°C. Protect from light and moisture.
 - Keep medicines out of reach of children.
- 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
VENLIFT ER 37.5 MG CAPSULE:
 Size “4” Peach/Translucent Peach, hard gelatin capsules, containing white to off-white pellets.

VENLIFT ER 75 MG CAPSULE:
 Size “2”, Yellow/translucent yellow, hard gelatin capsules, containing white to off-white pellets.

VENLIFT ER 150 MG CAPSULE:
 Size “0”, Orange/translucent orange, hard gelatin capsules, containing white to off-white pellets.

- Ingredients
 Active ingredient:
 - Venlafaxine hydrochloride.

Inactive ingredients:

- Sugar Globules (Seal coated 20/30#).
- HPMC 2910 E 15 LV (Hypromellose).
- Colloidal Silicon Dioxide (Aerosil 200).
- Ethyl Cellulose (45 CPS).
- Hydroxy Propyl methyl cellulose (HPMC 6 CPS).

- MAL number(s):
VENLIFT ER 37.5 MG CAPSULE:
 MAL17085005AZ

VENLIFT ER 75 MG CAPSULE:
 MAL17085006AZ

VENLIFT ER 150 MG CAPSULE:
 MAL17085007AZ

Manufacturer

TORRENT
 PHARMACEUTICALS
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 India.

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Product Registration Holder

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