

Forms and presentation

Venlax® XR 37.5: Extended release capsules: Box of 20 or 30. Venlax® XR 75: Extended release capsules: Box of 20 or 30. Venlax® XR 150: Extended release capsules: Box of 20 or 30.

Composition

Venlax® XR 37.5: Each extended release capsule contains Venlafaxine Hydrochloride equivalent to Venlafaxine 37.5 mg. Venlax® XR 75: Each extended release capsule contains Venlafaxine Hydrochloride equivalent to Venlafaxine 75 mg. Venlax® XR 150: Each extended release capsule contains Venlafaxine Hydrochloride equivalent to Venlafaxine 150 mg. Excipients: mannitol, sucrose, starch, ethyl cellulose, hydroxpropyl methyl cellulose, gelatin, titanium dioxide (Venlax[®] XR 37.5, Venlax[®] XR 75), quinoline yellow (Venlax[®] XR 75, Venlax® XR 150), sunset yellow (Venlax® XR 37.5, Venlax® XR 75), brilliant blue (Venlax® XR 150).

Why should you take Venlax® XR?

Therapeutic class: Psychoanaleptics.

ATC code: N06AX16.

Venlax® XR is indicated for:

- · Treatment of major depressive disorder (acute depressive episodes, recurrent or chronic depression).
- · Generalized or social anxiety disorder.
- · Panic disorder.

What are the cases in which you should not take Venlax® XR?

Do not take Venlax® XR if you are allergic to venlafaxine hydrochloride or to one of the excipients.

Precautions for the use of Venlax® XR

- · Periodic medical examinations are necessary during long term use of this medication.
- · Avoid the use of alcoholic beverages or the intake of other CNS depressants (unless prescribed by the physician).
- Possible dizziness or lightheadedness; caution when getting up suddenly from a lying or sitting position.
- Possible blurred vision, drowsiness, impairment of judgment, thinking, or motor skills; caution when driving or doing jobs requiring alertness.
- Up to 4 weeks or more of therapy may be required before antidepressant effects are achieved.
- · Contact your physician before stopping or reducing your dosage.

What are the side effects of Venlax® XR?

Like any other medication Venlax® XR may cause unpleasant effects in some people such as:

abnormal dreams, abnormal ejaculation, constipation, dizziness, dry mouth, headache, insomnia, nausea, nervousness, sleepiness, sweating, weakness, weight loss.

Are there any drug or food interactions with Venlax® XR?

To avoid potential interactions between several medications inform your physician or pharmacist before combining Venlax® XR with any of the following drugs: lithium, cimetidine, indinavir, serotoninergic drugs, monoamine oxidase inhibitors and other CNS-active drugs.

No food interactions have been reported with Venlax® XR.

Avoid alcohol consumption while taking Venlax® XR due to the possibility of additive psychomotor impairment.

Also, the possibility of an increase in undesirable effects should be considered if Venlax® XR is used in combination with the herbal remedy St. John's Wort.

Pregnancy and lactation

Since no adequate data on the use in pregnant women is available, Venlax® XR should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the fetus.

Venlax® XR is secreted in breast milk thus breast feeding is not recommended during therapy.

What is the recommended dosage of Venlax® XR?

The usual starting dose of Venlax® XR is 75 mg once daily, taken with food (some people begin with 37.5 mg for the first 4 to 7 days). This dose is gradually increased up to a maximum of 225mg per day. The dosage of Venlax® XR is determined individually and adapted to the patient's condition and response.

How should you take Venlax® XR?

Venlax® XR is taken as a single daily dose, at the same time each day, either in the morning or in the evening. Venlax® XR capsule should be swallowed with a sufficient amount of water but not divided, crushed, or chewed.

It is preferred to take Venlax® XR with food to lessen gastrointestinal side effects.

Duration of treatment

During long-term therapy for any indication, Venlax® XR dosage should be maintained at the lowest effective dose and the need for continuing treatment should be periodically reassessed.

What to do in the event of overdosage?

It is advisable to contact your physician if you suspect an overdose. Symptoms of overdose include: sleepiness, vertigo, rapid or slow heartbeat, low blood pressure, seizures, coma.

What to do if you miss a dose?

Take the missed dose as soon as you remember; if it is almost time for your next dose, skip the dose you missed and go back to your regular schedule. Never take several doses at the same time.

Storage

Store below 30°C.

Keep in original pack in intact conditions.

Do not take after the expiry date indicated on the outer packaging.

Revision Date: January 2019.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the
- instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor

Medicament: keep out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacists

> Benta SAL Dbaveh - Lebanon