

#### 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  $Venlax^{\otimes}$  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<sup>®</sup> 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<sup>®</sup> 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
Dbayeh - Lebanon