

Summary Public Assessment Report

Venlafaxin Liconsa / Venlafaxin 1A Farma / Venlafaxin Medical Valley (venlafaxine hydrochloride)

SE/H/564/05/DC

SE/H/581/05/DC

SE/H/582/05/DC

Summary Public Assessment Report

Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley
(venlafaxine hydrochloride)

prolonged-release tablet, 300 mg

This is a summary of the public assessment report (PAR) for Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley. It explains how Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley were assessed, and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley.

For practical information about using Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley, patients should read the package leaflet or contact their doctor or pharmacist.

What are Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley and what are they used for?

Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley are a 'hybrid medicine'. This means that they are similar to a reference medicine containing the same active substance, but with new strength. The company has provided additional own data to demonstrate the safety and efficacy of Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley regarding this difference from the reference medicine.

The reference medicine for Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley is Efexor Depot, Prolonged-release capsule, hard 150 mg. Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley are used in the Treatment of major depressive episodes and for prevention of recurrence of major depressive episodes.

How do Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley work?

Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley contains the active substance venlafaxine, which is an antidepressant that belongs to a group of medicines called serotonin and norepinephrine reuptake inhibitors (SNRIs). This group of medicines are used to treat depression and other conditions such as anxiety disorders. It is thought that people who are depressed and/or anxious 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.

How are Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley used?

The pharmaceutical form of Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley are prolonged-release tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley have been shown in studies?

Because Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley are a hybrid application and are considered to be therapeutically equivalent, to the reference product Efexor Depot, Prolonged-release capsule, hard 150 mg, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley?

For the full list of all side effects reported with Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why are Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley approved?

These medicines are similar to a reference medicine containing the same active substance, but are available as other strength. The company has provided additional own data to demonstrate the safety and efficacy of Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley regarding this difference from the reference medicine.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley's benefits are greater than their risks and recommended that they are approved for use.

What measures are being taken to ensure the safe and effective use of Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley?

A risk management plan has been developed to ensure that Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley are used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley

The marketing authorisation for Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley was granted on 2019-02-11 in Sweden.

The full PAR for Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Venlafaxin Liconsa, Venlafaxin 1A Farma and Venlafaxin Medical Valley, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2019-04.