LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Venlafaxin Liconsa
(venlafaxine)

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venlafaxine

Prolonged-release tablet, 37,5 mg; 75 mg; 150 mg; 225 mg

This is a summary of the public assessment report (PAR) for Venlafaxin Liconsa. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Venlafaxin Liconsa and what is it used for?
The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as another pharmaceutical form, prolonged-release tablets, and with a different strength (225 mg only).

The reference medicine for the product is Efexor Depot.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

Venlafaxin Liconsa is used to treat adults with depression. Treating depression properly is important to help you get better. If it is not treated, your condition may not go away and may become more serious and more difficult to treat.

How does Venlafaxin Liconsa work?
Venlafaxin Liconsa 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 is 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 is Venlafaxin Liconsa used?
The pharmaceutical form is a 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 in Sweden.

What benefits of Venlafaxin Liconsa have been shown in studies?
Studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Efexor Depot. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Venlafaxin Liconsa?
For the full list of side effects, see section 4 of the package leaflet.

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

Why is Venlafaxin Liconsa approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and to be similar with the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Efexor Depot, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Venlafaxin Liconsa?
A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, 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
The full PAR for Venlafaxin Liconsa can be found on the following website: MRI - Home. For more information about treatment with Venlafaxin Liconsa, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2026-05