

Summary Public Assessment Report

Efexor Depot (venlafaxine hydrochloride)

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(venlafaxine hydrochloride)

Prolonged-release capsules; 225 mg

This is a summary of the public assessment report (PAR) for Efexor Depot. It explains how Efexor Depot was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Efexor Depot.

For practical information about using Efexor Depot, patients should read the package leaflet or contact their doctor or pharmacist.

What is Efexor Depot and what is it used for?

Efexor Depot is a treatment for adults with depression. It is also a treatment for adults with the following anxiety disorders: generalised anxiety disorder, social anxiety disorder (fear or avoidance of social situations) and panic disorder (panic attacks). Treating depression or anxiety disorders 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.

Efexor depot 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.

How does Efexor Depot work?

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 Efexor Depot used?

The pharmaceutical form of Efexor Depot is prolonged-release capsules 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 Efexor Depot have been shown in studies?

Efexor Depot 225 mg is a new higher strength compared to the already approved lower strengths of Efexor Depot. The company's own data on efficacy and safety studies previously approved for the lower strengths is applicable for Efexor Depot 225 mg as well. Therefore, it is considered that Efexor Depot is effective in treating adults with depression and the following anxiety disorders: generalised anxiety disorder, social anxiety disorder (fear or avoidance of social situations) and panic disorder (panic attacks).

What are the possible side effects of Efexor Depot?

For the full list of all side effects reported with Efexor Depot, see section 4 of the package leaflet.

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

Why is Efexor Depot approved?

The effect of Efexor Depot 225 mg in the treatment of adults with depression and the following anxiety disorders: generalised anxiety disorder, social anxiety disorder (fear or avoidance of social situations) and panic disorder (panic attacks) was considered to be the same as the effect of the previously approved lower strengths of Efexor Depot. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Efexor Depot's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Efexor Depot?

A risk management plan has been developed to ensure that Efexor Depot 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 for Efexor Depot, 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 Efexor Depot

The marketing authorisation for Efexor Depot was granted on 2014-11-20 in Sweden.

The full PAR for Efexor Depot can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Efexor Depot, please read the [package leaflet](#) on MPA website or contact your doctor or pharmacist.

This summary was last updated in 2014-11-20.