

Summary Public Assessment Report

Venlafaxin Pfizer (venlafaxine hydrochloride)

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(venlafaxine hydrochloride)

prolonged release capsule, hard, 37.5 mg, 75 mg and 150 mg

This is a summary of the public assessment report (PAR) for Venlafaxin Pfizer. It explains how Venlafaxin Pfizer 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 Venlafaxin Pfizer.

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

What is Venlafaxin Pfizer and what is it used for?

Venlafaxin Pfizer is a 'generic medicine'. This means that Venlafaxin Pfizer is similar to a 'reference medicine' already authorised in the European Union (EU) called Efexor Depot.

Venlafaxin Pfizer is used in the 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.

How does Venlafaxin Pfizer work?

Venlafaxin Pfizer 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 Pfizer used?

The pharmaceutical form of Venlafaxin Pfizer is prolonged release capsules, hard, 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 Pfizer have been shown in studies?

No additional studies were needed as the generic medicinal product will have the same qualitative and quantitative composition and will be manufactured at the same manufacturing site, using the same manufacturing process and the same source of active substance as the 'reference medicine' called Efexor Depot.

What are the possible side effects of Venlafaxin Pfizer?

Because Venlafaxin Pfizer is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Venlafaxin Pfizer approved?

It was concluded that, in accordance with EU requirements, Venlafaxin Pfizer has been shown to have comparable quality and to be similar to the reference medicine Efexor Depot. Therefore, the Medical Products Agency in Sweden 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 Pfizer?

A risk management plan has been developed to ensure that Venlafaxin Pfizer 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 Venlafaxin Pfizer, 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 Pfizer

The marketing authorisation for Venlafaxin Pfizer was granted on 2015-01-29 in Sweden.

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

This summary was last updated in 2015-01-29.