

Summary Public Assessment Report

Venlafaxin Medical Valley (venlafaxine)

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(venlafaxine)

Prolonged release tablets
75, 150 and 225 mg

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

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

What is Venlafaxin Medical Valley and what is it used for?

Venlafaxin Medical Valley 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 instead of prolonged release capsule, hard).

The reference medicine for Venlafaxin Medical Valley is Efexor Depot.

Venlafaxin Medical Valley is a treatment for adults with depression. Venlafaxin Medical Valley 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).

How does Venlafaxin Medical Valley work?

Venlafaxin Medical Valley 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 Medical Valley used?

The pharmaceutical form of Venlafaxin Medical Valley is prolonged release tablets 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 Medical Valley have been shown in studies?

Studies in patients 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 of Venlafaxin Medical Valley?

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

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

Why is Venlafaxin Medical Valley approved?

This medicine is similar to a reference medicine containing the same active substance, but is available as prolonged release tablets (instead of prolonged release capsule, hard).

It was concluded that, in accordance with EU requirements, Venlafaxin Medical Valley has been shown to have comparable quality and to be bioequivalent 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 Medical Valley?

A risk management plan has been developed to ensure that Venlafaxin Medical Valley 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 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 Medical Valley

The marketing authorisation for Venlafaxin Medical Valley was granted 2008-07-18 in Sweden.

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

This summary was last updated in 2017-02.