LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pregabalin Medical Valley (pregabalin)

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Pregabalin Medical Valley

(pregabalin)

Capsule, hard, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg and 300 mg

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

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

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

Pregabalin Medical Valley is a 'generic medicine'. This means that Pregabalin Medical Valley is similar to a 'reference medicine' already authorised in the European Union (EU) called Lyrica.
Pregabalin Medical Valley belongs to a group of medicines used to treat epilepsy and Generalised Anxiety Disorder (GAD) in adults.

How is Pregabalin Medical Valley used?

The pharmaceutical form of Pregabalin Medical Valley is capsule, 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 Pregabalin Medical Valley have been shown in studies?

Because Pregabalin Medical Valley is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Lyrica. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Pregabalin Medical Valley?

Because Pregabalin Medical Valley is a generic medicine and is bioequivalent to the reference 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 Pregabalin Medical Valley approved?

It was concluded that, in accordance with EU requirements, Pregabalin Medical Valley has been shown to have comparable quality and to be bioequivalent to the reference medicine Lyrica. Therefore, the Medical Products Agency in Sweden decided that, as for Lyrica, 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 Pregabalin Medical Valley?

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

The marketing authorisation for Pregabalin Medical Valley was granted on 2016-03-31 in Sweden.

The full PAR for Pregabalin Medical Valley can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Pregabalin Medical Valley, please read the Package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-03.