Summary Public Assessment Report

Generics

Pregamid 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules

(pregabalin)

NL/H/3245/001-008/DC

Date: 27 July 2016

Summary Public Assessment Report

Generics

Pregamid hard capsules
Active substance: pregabalin

This is a summary of the public assessment report (PAR) for Pregamid. It explains how this medicine 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 Pregamid.

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

What is Pregamid and what is it used for?
Pregamid is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Lyrica.

This medicine is used to treat adults with the following conditions:

- epilepsy, where it is used as an 'add-on' to existing treatment in patients who have partial seizures (epileptic fits starting in one specific part of the brain) that cannot be controlled with their current treatment;
- generalised anxiety disorder (long-term anxiety or nervousness about everyday matters).

Pregabalin is also used to treat neuropathic pain (pain due to nerve damage), including peripheral neuropathic pain, such as the pain experienced by patients with diabetes or herpes zoster (shingles), and central neuropathic pain, such as the pain experienced by patients who have had a spinal cord injury. Usage of pregabalin in this condition is patented by another company.

How does this medicine work?
The active substance pregabalin is similar in structure to the body's own 'neurotransmitter' gamma−amino butyric acid (GABA), but has very different biological effects. Neurotransmitters are chemicals that allow nerve cells to communicate with each other. The exact way that pregabalin works is not fully understood, but it is thought to affect the way that calcium enters nerve cells. This reduces the activity of some of the nerve cells in the brain and spinal cord, reducing the release of other neurotransmitters that are involved in pain, epilepsy and anxiety.

How is this medicine used?
The pharmaceutical form of pregamid is a capsule and the route of administration is by mouth (oral). The medicine can only be obtained with a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Pregamid 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 this medicine?
Because Pregamid is a generic medicine and is bioequivalent to the reference medicine, Lyrica, its benefits and possible side effects are taken as being the same as the reference medicine.

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

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines

Evaluation Board of the Netherlands decided that, as for the reference medicine Lyrica, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Pregamid, 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 this medicine
In the Netherlands, the marketing authorisation for Pregamid was granted on 20 July 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/human. For more information about treatment with Pregamid, read the package leaflet (http://mri.medagencies.org/download/NL_H_3245_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in July 2016.