LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pregabalin Jubilant (pregabalin)

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Summary Public Assessment Report

Pregabalin Jubilant
(pregabalin)

Hard capsule 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg

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

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

What is Pregabalin Jubilant and what is it used for?

Pregabalin Jubilant is a 'generic medicine'. This means that Pregabalin Jubilant is similar to a 'reference medicine' already authorised in the European Union (EU) called Lyrica®.

Pregabalin Jubilant belongs to a group of medicines used to treat epilepsy, neuropathic pain and generalised anxiety disorder (GAD) in adults.

How does Pregabalin Jubilant work?

The active substance in Pregabalin Jubilant, 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 Pregabalin Jubilant used?

The pharmaceutical form of Pregabalin Jubilant is hard 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 Pregabalin Jubilant have been shown in studies?

No additional studies were needed as Pregabalin Jubilant is a generic medicine considered to be 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 Jubilant?

Because Pregabalin Jubilant 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 Jubilant approved?

It was concluded that, in accordance with EU requirements, Pregabalin Jubilant 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 Jubilant?

A risk management plan has been developed to ensure that Pregabalin Jubilant 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 Jubilant, 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 Jubilant

The marketing authorisation for Pregabalin Jubilant was granted on 2019-08-15 in Sweden.

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

This summary was last updated in 2019-11.