LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Levetiracetam Krka
(Levetiracetam)

SE/H/1067/01-04/E01

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Levetiracetam Krka

(levetiracetam)

film-coated tablets, 250 mg, 500 mg, 750 mg and 1000 mg

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

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

What is Levetiracetam Krka and what is it used for?

Levetiracetam Krka is a 'generic medicine'. This means that Levetiracetam Krka is similar to a 'reference medicine' already authorised in the European Union (EU) called Keppra.

Levetiracetam Krka is used:

- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat partial onset seizures with or without secondary generalisation.
- as an add-on to other antiepileptic medicines.

How does Levetiracetam Krka work?

Levetiracetam Krka is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

How is Levetiracetam Krka used?

The pharmaceutical form of Levetiracetam Krka is film-coated 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 Levetiracetam Krka have been shown in studies?

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

What are the possible side effects of Levetiracetam Krka?

Because Levetiracetam Krka 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 Levetiracetam Krka approved?

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

A risk management plan has been developed to ensure that Levetiracetam Krka 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 Levetiracetam Krka, 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 Levetiracetam Krka

The marketing authorisation for Levetiracetam Krka was granted on 2011-10-07 in Sweden.

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

This summary was last updated in 2015-01.