LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Brivaracetam Glenmark (brivaracetam)

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Summary Public Assessment Report

Brivaracetam Glenmark
brivaracetam

Film-coated tablet, 10 mg, 25 mg, 50 mg, 75 mg, 100 mg

This is a summary of the public assessment report (PAR) for Brivaracetam Glenmark. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Brivaracetam Glenmark and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Briviact.

Brivaracetam Glenmark contains the active substance brivaracetam. It belongs to a group of medicines called 'anti-epileptics'. These medicines are used to treat epilepsy.

Brivaracetam Glenmark is used in adults, adolescents and children from 2 years of age.

How does Brivaracetam Glenmark work?

- Brivaracetam Glenmark is used to treat a type of epilepsy that has partial seizures with or without a secondary generalisation.
- Partial seizures are fits that start by only affecting one side of the brain. These partial seizures can spread and extend to larger areas on both sides of the brain – this is called a 'secondary generalisation'.
- Patients are given this medicine to lower the number of fits (seizures) they have.
- Brivaracetam Glenmark is used together with other medicines for epilepsy.

How is Brivaracetam Glenmark used?

The pharmaceutical form is film-coated tablet 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 in Sweden.

What benefits of Brivaracetam Glenmark have been shown in studies?

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

What are the possible side effects from Brivaracetam Glenmark?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Brivaracetam Glenmark approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Briviact, 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 Brivaracetam Glenmark?

A risk management plan has been developed to ensure that the product 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, 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 Brivaracetam Glenmark

The full PAR for Brivaracetam Glenmark can be found on the following website: MRI - Home. For more information about treatment with Brivaracetam Glenmark, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-05.