LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Shaktatin
(gabapentin)

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Summary Public Assessment Report

Shaktatin
gabapentin

Oral solution, 50 mg/ml

This is a summary of the public assessment report (PAR) for Shaktatin. 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 Shaktatin and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available in a different strength.

The reference medicine for the product is Neurontin.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

The product is used in the treatment of:

- Various forms of epilepsy (seizures that are initially limited to certain parts of the brain, whether the seizure spreads to other parts of the brain or not). The doctor will prescribe Shaktatin to help treat epilepsy when the current treatment is not fully controlling the condition. Shaktatin should be taken in addition to current treatment unless told otherwise. Shaktatin can also be used on its own to treat adults and children over 12 years of age.
- Peripheral neuropathic pain (long-lasting pain caused by damage to the nerves). A variety of different diseases can cause peripheral neuropathic pain (primarily occurring in the legs and/or arms), such as diabetes or shingles. Pain sensations may be described as hot, burning, throbbing, shooting, stabbing, sharp, cramping, aching, tingling, numbness, pins and needles etc.

How does Shaktatin work?

Shaktatin contains the active substance gabapentin which belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long-lasting pain caused by damage to the nerves).

How is Shaktatin used?

The pharmaceutical form is solution 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 Shaktatin have been shown in studies?

Because the product is a hybrid application of Neurontin, clinical studies have been provided for Shaktatin to show efficacy for the difference of Shaktatin from the reference product Neurontin.

What are the possible side effects from Shaktatin?

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 Shaktatin approved?

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

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 Shaktatin

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

This summary was last updated in 2025-04.