

Summary Public Assessment Report

Gabapentin Orion (gabapentin)

SE/H/2083/01-02/E/01

This module reflects the scientific discussion for the approval of Gabapentin Orion. The Summary Public Assessment Report was written in 05-2018 by the previous RMS DK after initial procedure DK/H/2722/001-002/DC. RMS transfer from DK to SE was completed 2020-05-06.

Summary Public Assessment Report

Gabapentin Orion

gabapentin, hard capsules 300 mg and 400 mg

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

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

What is Gabapentin Orion and what is it used for?

Gabapentin Orion is a 'generic medicine'. This means that Gabapentin Orion is similar to a 'reference medicine' already authorised in the European Union (EU) called Neurontin.

Gabapentin Orion 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). Your doctor will prescribe Gabapentin Orion for you to help treat your epilepsy when your current treatment is not fully controlling your condition. You should take Gabapentin Orion in addition to your current treatment unless told otherwise. Gabapentin Orion 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 Gabapentin Orion work?

Gabapentin Orion belongs to a group of medicines used to treat epilepsy and peripheral neuropathic pain (long lasting pain caused by damage to the nerves). It is not known precisely how it works.

How is Gabapentin Orion used?

The pharmaceutical form of Gabapentin Orion is hard capsules and the route of administration is oral.

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

For treatment of epilepsy, the recommended dose is:

Adults and adolescents

The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3,600 mg each day

and your doctor will tell you to take this in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

Children aged 6 years and above

The dose to be given to your child will be decided by your doctor as it is calculated against your child's weight. The treatment is started with a low initial dose which is gradually increased over a period of approximately 3 days. The usual dose to control epilepsy is 25–35 mg per kg of body weight per day. It is usually given in 3 separate doses, usually once in the morning, once in the afternoon and once in the evening.

Gabapentin Orion is not recommended for use in children below 6 years of age.

For treatment of peripheral neuropathic pain, the recommended dose is

Adults

The starting dose will generally be between 300 mg and 900 mg each day. Thereafter, the dose may be increased as instructed by your doctor, up to a maximum of 3,600 mg each day and your doctor will tell you to take this in 3 separate doses, i.e. once in the morning, once in the afternoon and once in the evening.

If you have kidney problems or are receiving haemodialysis

Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys or are undergoing haemodialysis.

If you are an elderly patient (over 65 years of age)

You should take the normal dose of Gabapentin Orion unless you have problems with your kidneys. Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.

The medicine can only be obtained with a prescription.

What benefits of Gabapentin Orion have been shown in studies?

Because Gabapentin Orion is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Neurontin. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. The company provided data from the published literature on gabapentin.

What are the possible side effects of Gabapentin Orion?

Because Gabapentin Orion 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 Gabapentin Orion approved?

It was concluded that, in accordance with EU requirements, Gabapentin Orion has been shown to have comparable quality and to be bioequivalent to Neurontin. Therefore, the Danish Health and Medicines Authority decided that, as for Neurontin, 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 Gabapentin Orion?

A risk management plan has been developed to ensure that Gabapentin Orion 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 Gabapentin Orion, 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 Gabapentin Orion

The marketing authorisation for Gabapentin Orion was granted on 03-01-2018.

The full PAR and the package leaflet for Gabapentin Orion can be found on the website <http://mri.medagencies.org/Human/>. For more information about treatment with Gabapentin Orion, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 05-2018.