

Summary Public Assessment Report

Eletriptan Orion (eletriptan hydrobromide)

SE/H/1743/01-02/DC

Summary Public Assessment Report

Eletriptan Orion
(eletriptan hydrobromide)

Film-coated tablets, 20 mg and 40 mg

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

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

What is Eletriptan Orion and what is it used for?

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

Eletriptan Orion can be used to treat migraine headache with or without aura in adults. Before the start of a migraine headache, you may experience a phase called an aura, which can involve vision disorders, numbness and speech disorders.

How does Eletriptan Orion work?

Eletriptan Orion contains the active substance eletriptan. Eletriptan Orion is one of a group of medicines called serotonin receptor agonists. Serotonin is a natural substance found in the brain that helps to narrow the blood vessels.

How is Eletriptan Orion used?

The pharmaceutical form of Eletriptan Orion 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.

What benefits of Eletriptan Orion have been shown in studies?

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

What are the possible side effects of Eletriptan Orion?

Because Eletriptan 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 Eletriptan Orion approved?

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

A risk management plan has been developed to ensure that Eletriptan 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 Eletriptan 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 Eletriptan Orion

The marketing authorisation for Eletriptan Orion was granted on 2018-10-02 in Sweden.

The full PAR for Eletriptan Orion can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Eletriptan Orion, please read the [\[package leaflet\]](#) or contact your doctor or pharmacist.

This summary was last updated in 2018-10.