

Summary Public Assessment Report

Eslicarbazepine Accord (eslicarbazepine acetate)

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Eslicarbazepinacetat Accord
eslicarbazepine acetate

Tablet, 200 mg, 800 mg

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

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

What is Eslicarbazepinacetat Accord and what is it used for?

Eslicarbazepinacetat Accord is a 'generic medicine'. This means that Eslicarbazepinacetat Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Zebinix.

Eslicarbazepineacetat Accord belongs to a group of medicines called antiepileptics used to treat epilepsy, a condition where someone has repeated seizures or fits. Eslicarbazepineacetat Accord is used to reduce the number of seizures.

Eslicarbazepinacetat Accord is used:

- on its own (monotherapy) in adult patients with newly diagnosed epilepsy
- with other antiepileptic medicines (adjunctive therapy), in adult, adolescents and children patients above 6 years of age, who are experiencing seizures that affect one part of the brain (partial seizure). These seizures may or may not be followed by a seizure affecting all of the brain (secondary generalisation).

How does Eslicarbazepinacetat Accord work?

The active substance, eslicarbazepine acetate is converted into eslicarbazepine in the body. Epilepsy is caused by excessive electrical activity in the brain. For electrical impulses to travel along nerves there needs to be a rapid movement of sodium into the nerve cells. The precise mechanism of action of eslicarbazepine is not known, but it is thought to work by blocking 'voltage-gated sodium channels', which stops sodium entering the nerve cells. This reduces the activity of the nerve cells in the brain, reducing the intensity and the number of seizures.

How is Eslicarbazepinacetat Accord used?

The pharmaceutical form of Eslicarbazepinacetat Accord is 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 Eslicarbazepinacetat Accord have been shown in studies?

Because Eslicarbazepinacetat Accord is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Zebinix.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Eslicarbazepinacetat Accord?

Because Eslicarbazepinacetat Accord 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 restrictions, see the package leaflet.

Why is Eslicarbazepinacetat Accord approved?

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

A risk management plan has been developed to ensure that Eslicarbazepinacetat Accord 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 Eslicarbazepinacetat Accord, 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 Eslicarbazepinacetat Accord

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

This summary was last updated in YYYY-MM.
Infoga datum enligt när sPAR blir klar för publicering.