LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fosphenytoin Eugia
(fosphenytoin sodium)

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Summary Public Assessment Report

Fosphenytoin Eugia
fosphenytoin sodium

Concentrate for solution for injection/infusion, 75 mg/ml (50 mg FE/ml)

This is a summary of the public assessment report (PAR) for Fosphenytoin Eugia. 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 Fosphenytoin Eugia 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 Pro-Epanutin.

The product is used in the treatment of epilepsy in adults and children aged 5 years and older:

- to contol severe epileptic seizure (fits) so called status epilepticus, of the tonic-clonic (grand mal) type.
- to control or prevent seizures during or after brain surgery and/or head injury.
- to control or prevent seizures for short periods of time when antiepileptic medicines cannot be taken by mouth.

How does Fosphenytoin Eugia work?

Fosphenytoin Eugia contains the active substance fosphenytoin which belongs to a group of medicines called anti-epileptics.

How is Fosphenytoin Eugia used?

The pharmaceutical form is concentrate for solution for injection/infusion.

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

What benefits of Fosphenytoin Eugia have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Pro-Epanutin.

What are the possible side effects from Fosphenytoin Eugia?

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 Fosphenytoin Eugia 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 Pro-Epanutin, 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 Fosphenytoin Eugia?

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 Fosphenytoin Eugia

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

This summary was last updated in 2022-12-13.