LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Oxaliplatin Eugia
(oxaliplatin)

SE/H/2172/01/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Oxaliplatin Eugia
oxaliplatin

concentrate for solution for infusion, 5 mg/ml

This is a summary of the public assessment report (PAR) for Oxaliplatin 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 Oxaliplatin 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 Eloxatin.

Oxaliplatin Eugia is used to treat advanced cancer of the large bowel (especially after complete resection of primary tumour, and metastatic cancer (cancer cells that spreads to other parts of the body) of colon and rectum).

How does Oxaliplatin Eugia work?

Oxaliplatin Eugia contains active ingredient oxaliplatin which belongs to a group of medicines based on platinum, which are used to treat cancer. Oxaliplatin exhibits a wide spectrum of antitumour activity in a variety of tumour model systems including human colorectal cancer models. Oxaliplatin Eugia is used in combination with other anticancer medicines called 5-fluorouracil and folinic acid.

How is Oxaliplatin Eugia used?

The pharmaceutical form is concentrate for solution for infusion.

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 Oxaliplatin Eugia have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Eloxatin.

What are the possible side effects from Oxaliplatin 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 Oxaliplatin Eugia approved?

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

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

This summary was last updated in 2023-04.