LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Carboplatin Accord (carboplatin)

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Summary Public Assessment Report

Carboplatin Accord
carboplatin

Concentrate for solution for infusion, 10 mg/ml

This is a summary of the public assessment report (PAR) for Carboplatin Accord. 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 Carboplatin Accord 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 Paraplatin, 10 mg/ml, concentrate for solution for infusion.

The product is used in the treatment of some types of lung cancer and ovarian cancer.

How does Carboplatin Accord work?

Carboplatin Accord is an anti-cancer medicine. Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy.

How is Carboplatin Accord 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 Carboplatin Accord 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, Paraplatin, 10 mg/ml, concentrate for solution for infusion.

What are the possible side effects from Carboplatin Accord?

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 Carboplatin Accord approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Paraplatin, 10 mg/ml, concentrate for solution for infusion, 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 Carboplatin Accord?

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 Carboplatin Accord

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

This summary was last updated in YYYY-MM.