Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Carboplatin 10 mg/ml concentrate for solution for infusion

carboplatin

PL 56284/0011

Eugia (UK) Limited

LAY SUMMARY

Carboplatin 10 mg/ml concentrate for solution for infusion carboplatin

This is a summary of the Public Assessment Report (PAR) for Carboplatin 10 mg/ml concentrate for solution for infusion. It explains how this product 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 this product.

This product will be referred to as Carboplatin in this lay summary for ease of reading.

This product has been authorised by Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 18 July 2023 (PT/H/2544/001/DC). This is known as the MR/DC Reliance Procedure.

This application was approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10.1 of Directive 2001/83/EC, as amended).

For practical information about using Carboplatin, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Carboplatin and what is it used for?

This product is a generic medicine. This means that this medicine is the same as, and considered interchangeable with, a reference medicine already authorised, called Paraplatin 10 mg/ml concentrate for solution for infusion.

Carboplatin is used against advanced cancer of the ovary and small cell cancer of the lung.

How does Carboplatin work?

Carboplatin contains active ingredient, carboplatin, which belong to a group of medicines known as platinum coordination compounds, which are used to treat cancer.

How is Carboplatin used?

The pharmaceutical form of this medicine is a concentrate for solution for infusion, and the route of administration is intravenous use (into a vein).

This medicine will always be administered by nurse or doctor. It is usually given in a drip by slow injection into a vein and will usually take between 15 and 60 minutes to be administered.

The dose will be dependent on patient's height and weight, function of their blood (haematopoietic) system and their kidney function. The patient's doctor will choose the best dose for them. The infusion will normally be diluted before use.

Adult

The usual dose is 400 mg/m² of the body surface area (calculated from the patient's height and weight).

Elderly
The usual adult doses may be used although the doctor may choose to use a different dose.

Kidney problems
The amount given may vary, according to how well the patient's kidneys are working. If the patient suffers from kidney problems your doctor may reduce the dose and may perform frequent blood test as well as monitoring your kidney function. This medicine will be given by a doctor experienced in the use of cancer treatment.

Children and adolescents
There has not been enough usage of Carboplatin in children to allow the recommendation of specific dose.

The patient may feel sick while they are being treated with Carboplatin. The patient's doctor may give them another medicine to reduce these effects before they are treated with this medicine.

There will be a usual gap of 4 weeks between each dose of Carboplatin. The patient's doctor will want to perform some blood tests each week after giving this medicine to decide the correct next dosage for the patient.

For further information on how Carboplatin is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the MHRA website.

This medicine can only be obtained with a prescription.

The patient should ask the administering healthcare practitioner if they have any questions concerning their medicine.

What benefits of Carboplatin have been shown in studies?
Carboplatin is a generic medicine that fulfils criteria meaning that no additional studies are required. Carboplatin has been considered a generic medicine of the reference medicine based on a comparison of their physical and chemical characteristics.

What are the possible side effects of Carboplatin?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Because Carboplatin is a generic medicine and is comparable to the reference medicine, its benefits and possible side effects are considered to be the same as the reference medicines.

Why was Carboplatin approved?
It was concluded that Carboplatin has been shown to be comparable to the reference medicine. Therefore, the MHRA decided that the benefits are greater than the risks and recommended that this medicine can be approved for use.

What measures are being taken to ensure the safe and effective use of Carboplatin?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Carboplatin. The RMP details the important risks of Carboplatin, how these risks can be minimised, any uncertainties about Carboplatin (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Carboplatin.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Carboplatin are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Carboplatin
A marketing authorisation was granted in the United Kingdom on 09 July 2024.

The full PAR for Carboplatin follows this summary.

This summary was last updated in July 2024.

TABLE OF CONTENTS

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Carboplatin 10 mg/ml concentrate for solution for infusion (PL 56284/0011) could be approved.

Carboplatin 10 mg/ml concentrate for solution for infusion is approved for the treatment of:

1) Advanced ovarian carcinoma of epithelial origin in:
    a. first line therapy
    b. second line therapy, after other treatments have failed.
2) Small cell carcinoma of the lung.

Carboplatin is an antineoplastic agent. Its activity has been demonstrated against several murine and human cell lines. Carboplatin exhibited comparable activity to cisplatin against a wide range of tumours regardless of implant site.

Mechanism of action

Alkaline elution techniques and DNA binding studies have demonstrated the qualitatively similar modes of action of carboplatin and cisplatin. Carboplatin, like cisplatin, induces changes in the superhelical conformation of DNA, which is consistent with a "DNA shortening effect".

This product has been authorised by MHRA for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 18 July 2023 (PT/H/2544/001/DC). For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the DC procedures, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies website.

This application was approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10.1 of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly, and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 09 July 2024.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product(s) is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**