

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Carboplatin 10 mg/ml Concentrate for Solution for Infusion

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Carboplatin Concentrate for Solution for Infusion is and what it is used for
2. Before you use Carboplatin Concentrate for Solution for Infusion
3. How to use Carboplatin Concentrate for Solution for Infusion
4. Possible side effects
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6. Further information

1. WHAT CARBOPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

Carboplatin Concentrate for Solution for Infusion is an anti-cancer medicine (cytotoxic agent). Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy.

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

2. BEFORE YOU USE CARBOPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION

Do not use Carboplatin Concentrate for Solution for Infusion

- if you have shown signs of hypersensitivity (severe allergy) to carboplatin or similar platinum containing medicines in the past
- if you have severe kidney disease
- if you have fewer blood cells than normal (your doctor will check this with a blood test)
- if you have a tumour that bleeds
- if you plan to receive a yellow fever vaccination or have just received one

Tell your doctor if any of the above applies to you before this medicine is used.

Take special care with Carboplatin Concentrate for Solution for Infusion

- if you are pregnant or if there is a chance you may be pregnant
- if you are breast-feeding
- if you have mild renal disease. Your doctor will want to monitor you more regularly
- if you are elderly (over 65 years old)

- if you have been treated with cisplatin or similar anti-cancer medicines in the past, carboplatin may cause abnormalities in your nervous system, such as pins and needles or hearing and vision problems. Your doctor may regularly assess you

Tell your doctor if either of the above applies to you before this medicine is used.

Taking/using other medicines

Special care is needed if you are taking/using other medicines as some could interact with carboplatin, for example:

- medicines which can reduce the number of cells in your blood, at the same time as carboplatin, may require changes to the dosage and frequency of your carboplatin treatment
- some antibiotics called aminoglycosides, vancomycin or capreomycin, at the same time as carboplatin, may increase the risk of kidney or hearing problems
- some water tablets (diuretics), at the same time as carboplatin, may increase the risk of kidney or hearing problems
- warfarin (which thins the blood) at the same time as carboplatin, may alter the effect of the warfarin and may require an increase in frequency of blood coagulation monitoring
- live or live-attenuated vaccines (for yellow fever vaccine see section 2, Do not use Carboplatin Concentrate for Solution for Infusion)
- phenytoin and fosphenytoin (used to treat various types of convulsions and seizures), at the same time as carboplatin, may increase the risk of a seizure
- other medicines which decrease the activity of the immune system (e.g. cyclosporine, tacrolimus, sirolimus)

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Safety in pregnant and breast-feeding women has not been shown however data for use in animals suggests that carboplatin could be harmful to the foetus.

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding before being treated with this medicine. Your doctor will decide if you should receive this medicine.

Men and women receiving treatment with this drug are at risk of having reduced fertility.

Due to the possible risk of birth defects, male patients and female patients of childbearing potential should take contraceptive measures before and during treatment with carboplatin.

Men treated with this medicine are advised not to father a child during, and up to 6 months after treatment. Advice on conservation of sperm should be sought prior to treatment because of the possibility of irreversible infertility.

Ask your doctor or pharmacist for advice before taking any medicine.

Effects on fertility

Treatment with carboplatin may temporarily or permanently reduce fertility in men and women. Tell your doctor if you have concerns.

Driving and using machines

Do not drive or use machines if you experience any side effect which may lessen your ability to do so such as nausea, vomiting, worsening of eyesight, or changes to your vision and hearing.

3. HOW TO USE CARBOPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION

This medicine will be given by infusion (drip) into a vein over 15-60 minutes.

This medicine will be diluted before use.

Dose

Your doctor will work out the correct dose of carboplatin for you and how often it must be given.

The dose will depend on your medical condition, your size and how well your kidneys are working. Your dose may need to be changed if you are elderly depending on your physical condition. Your doctor will tell how well your kidneys are working using blood or urine samples.

There is not enough information about use in infants and children to give specific doses for them.

You will have regular blood tests after your dose of carboplatin. You may also have checks for nerve damage and hearing loss.

There is likely to be about 4 weeks between each dose of carboplatin.

If you are given too much or too little Carboplatin Concentrate for Solution for Infusion

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. POSSIBLE SIDE EFFECTS

Like all medicines, carboplatin can have side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint

- you may also experience low numbers of blood cells leading to tiredness, fatigue, appearing pale, shortness of breath, increased infections such as sore throat and high temperature, bruising or unexpected bleeding

These are serious side effects. You may need urgent medical attention.

Very common side effects (affects more than 1 user in 10)

- tiredness, shortness of breath and paleness caused by anaemia (a condition in which there is a decreased number of red blood cells)
- feeling sick (nausea) or being sick (vomiting)
- stomach pain and cramp
- unexpected bruising or bleeding

Tests may also show:

- changes in your red and white blood cells and platelets (myelosuppression)
- increase in the level of urea in your blood (which shows reduced kidney function)
- decrease in the level of sodium, potassium, calcium and magnesium in your blood
- decrease in renal creatinine clearance (which shows reduced kidney function)
- abnormal liver enzyme levels

Common side effects (affects 1 to 10 users in 100)

- signs of infection such as fever or sore throat
- flu-like symptoms
- severe allergic reactions (anaphylaxis/anaphylactic reactions)
- symptoms of severe allergic reaction including sudden wheeziness or tightness of chest, swelling of the eyelids, face or lips, facial flushing, low blood pressure, rapid heart beat, hives, shortness of breath, dizziness and anaphylactic shock
- tingling or numbness in your hands, feet, arms or legs
- burning or prickling sensation
- decreased bone and tendon reflex
- taste disturbance or loss of taste
- temporary worsening of eyesight or changes to your vision
- ringing in the ears or changes in your hearing
- heart disorders
- tightness of the chest or wheezing
- interstitial lung disease (a group of lung disorders in which the deep lung tissues become inflamed)
- diarrhoea or constipation
- sore lips or mouth ulcers (mucous membrane disorders)
- hair loss
- rash and/or itchy skin
- pain or discomfort in your bones, joints, muscles, or surrounding structures (musculoskeletal disorder)
- problems with your kidneys or urine
- extreme tiredness/weakness (asthenia)

Tests may also show:

- increased level of bilirubin and creatinine in your blood
- increased level of uric acid in your blood which may lead to gout

Rare side effects (affects 1 to 10 users in 10,000)

- temporary sight loss

Very rare side effects (affects less than 1 user in 10,000)

- scarring of the lungs which causes shortness of breath and/or cough (pulmonary fibrosis)

Other side effects with unknown frequencies

- cancers caused by treatment with carboplatin (secondary malignancies)
- feeling unwell with high temperature due to low levels of white blood cells (febrile neutropenia)
- haemolytic-uraemic syndrome (a disease characterised by acute renal failure)
- dry mouth, tiredness, and headache due to excessive loss of body water (dehydration)
- loss of appetite, anorexia
- stroke
- severely impaired liver function, damage or death of liver cells
- heart failure
- obstruction in blood vessel (embolism)
- changes in blood pressure (hypertension or hypotension)
- skin disorders such as hives, rash, skin redness (erythema), and itching
- swelling or soreness where the injection was given

Carboplatin may lead to problems with your blood, liver and kidneys. Your doctor will take blood samples to check for changes in liver enzymes, or electrolytes in your blood.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CARBOPLATIN CONCENTRATE FOR SOLUTION FOR INFUSION

Keep out of the sight and reach of children.

Expiry

This medicine must not be used after the expiry date which is stated on the vial label and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage

Do not store above 25°C.

The vials should be kept in the outer carton in order to protect from light.

6. FURTHER INFORMATION

What Carboplatin Concentrate for Solution for Infusion contains

The active substance is carboplatin. Each millilitre (ml) of solution contains 10 milligrams (mg) of carboplatin.

The other ingredient is Water for Injections.

What Carboplatin Concentrate for Solution for Infusion looks like and contents of the pack

Carboplatin Concentrate for Solution for Infusion is a clear, colourless solution for infusion which comes in glass containers called vials.

It may be supplied in packs containing:

- 1 x 50 mg/5 ml Clear glass and ONCO-TAIN™ vials
- 1 x 150 mg/15 ml Clear glass and ONCO-TAIN™ vials
- 1 x 450 mg/45 ml Clear glass and ONCO-TAIN™ vials
- 1 x 600 mg/60 ml Clear glass and ONCO-TAIN™ vials

Not all packs may be marketed.

Marketing authorisation holder and manufacturer responsible for batch release in Europe

Hospira UK Limited, Queensway, Royal Leamington Spa, Warwickshire, CV31 3RW, United Kingdom

This leaflet was last revised in 09/2014.

Carboplatin 10 mg/ml Concentrate for Solution for Infusion

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Carboplatin Concentrate for Solution for Infusion must be diluted before use.

Incompatibilities

Carboplatin may interact with aluminium to form a black precipitate. Needles, syringes, catheters or IV administration sets that contain aluminium parts which may come into contact with carboplatin, should not be used for the preparation or administration of the drug.

Carboplatin should be prepared for administration only by professionals who have been trained in the safe use of chemotherapeutic agents.

Transfer to syringes and infusion containers should be carried out only in the designated area. Personnel carrying out these procedures should be adequately protected with clothing, gloves and an eye shield.

Pregnant personnel are advised not to handle chemotherapeutic agents.

Contamination

In the event of contact of carboplatin with eyes or skin, wash affected area with copious amounts of water or normal saline. A bland cream may be used to treat transient stinging of skin. Medical advice should be sought if the eyes are affected.

In the event of a spillage, two operators should put on gloves and mop up the spilled material with a sponge kept for that purpose. In the event of a powder spillage, cover with a cloth and moisten with water before mopping up. Rinse the area twice with water. Put all solutions and sponges in a plastic bag, seal and label with the words 'CYTOTOXIC WASTE' and incinerate.

Disposal

Syringes, containers, absorbent materials, solutions and other material which have come into contact with carboplatin should be placed in a thick plastic bag or other impervious container and incinerated at 1000°C.