

Package leaflet: Information for the user

Carboplatin 10 mg/ml Concentrate for Solution for Infusion

carboplatin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Carboplatin is and what it is used for
2. What you need to know before you are given Carboplatin
3. How you are given Carboplatin
4. Possible side effects
5. How to store Carboplatin
6. Contents of the pack and other information

1. What Carboplatin is and what it is used for

Carboplatin concentrate contains the active ingredient carboplatin which belongs to a group of medicines known as platinum coordination compounds, which is used to treat cancer.

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

2. What you need to know before you are given Carboplatin

Do not use Carboplatin:

- if you are allergic to carboplatin or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to another drug that belongs to the group of platinum containing compound.
- if you are breast feeding.
- if you have severe problems with your kidney (creatinine clearance below 30 ml/min) and/or liver function.
- if you have an imbalance of your blood cells (severe myelosuppression).
- if you have a tumour that bleeds.
- If you plan to receive a yellow fever vaccination or have just received one.

If any of these apply to you and you have not already discussed this with your doctor or nurse, it is recommended to inform the doctor or nurse as soon as possible and before receiving Carboplatin.

Carboplatin is usually given to patients in hospital. Normally you must not handle this medicine. Your doctor or nurse will administer the medicine and will carefully and frequently monitor you during and after treatment. You will normally have blood tests before each administration.

Warnings and precautions

Talk to your doctor or nurse before using Carboplatin:

If you are pregnant or there is a chance you may be pregnant.

If you are breast-feeding.

If you are likely to drink alcohol whilst treated with this medicine.

If you are on radiotherapy.

If you have had or are due to have any vaccination including a live or live-attenuated vaccination.

If your kidneys are not working properly the effects of carboplatin on the blood (haematopoietic system) are increased and prolonged compared to patients with normal kidney function.

In patients with abnormal kidney function visual disturbances, including reversible loss of vision has been reported if carboplatin is used in dose higher than that recommended. The vision may recover totally or to a significant extent upon discontinuation of this medicine.

Your doctor will want to monitor you more regularly if your kidneys are not working properly.

Older people are more likely to experience side effect of the carboplatin on the blood count and nervous system.

If any of these apply to you and you have not already discussed this with your doctor or nurse, it is recommended to inform the doctor or nurse as soon as possible and before receiving the medicine.

This medicine may be diluted with another solution before it is administered. You must discuss this with your doctor and make sure that it is suitable for you.

Talk to your doctor or nurse before being given Carboplatin.

Other medicines and Carboplatin

Tell your doctor or nurse if you are using, have recently used or might use any other medicines.

You should tell your doctor if you are taking any of the following medicines as they may interact with Carboplatin:

- yellow fever vaccine and other live vaccines
- other medicines that are known to affect blood cell formation in the bone marrow
- other medicines that are known to be toxic to your kidney (e.g. aminoglycosides antibiotics, loop diuretics, vancomycin, capreomycin)

- other medicines that are known to damage the hearing or balance functions of the ear (e.g. aminoglycosides antibiotics, furosemide (loop diuretics), [used to treat heart failure and edema], vancomycin, capreomycin)
- other medicines which decrease the activity of the immune system (e.g cyclosporine, tacrolimus, sirolimus and other anticancer medicine)
- blood thinning medicines e.g. warfarin
- phenytoin and fosphenytoin (used to treat various types of convulsions and seizures)
- chelating agents (substances binding to carboplatin thereby decreasing the effect of carboplatin).

Carboplatin with alcohol

There is no known interaction between carboplatin and alcohol. However you must check with your doctor as carboplatin may affect the liver's ability to cope with alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If any of these apply to you and you have not already discussed this with your doctor or nurse, it is recommended to inform your doctor or nurse as soon as possible and before receiving this medicine.

Pregnancy

This medicine must not be used during pregnancy other than in the most exceptional circumstances in the treatment of cancer; where the potential benefit to the mother is considered to be greater than the risk to the unborn baby.

Breast-feeding

If treatment becomes necessary during the lactation period, breastfeeding must be stopped.

Fertility

Carboplatin can cause genetic damage. Women are advised to avoid becoming pregnant by using effective contraception before and during treatment. For women who are pregnant or become pregnant during therapy, genetic counselling should be provided.

Men treated with carboplatin 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 nurse for advice before using any medicine.

Driving and using machines

Carboplatin does not affect your ability to drive and use machines. However you should take extra care when you are given carboplatin especially if you are feeling and/or being sick, experiencing visual and hearing disturbances or feeling unsure of yourself.

3. How to use Carboplatin

Carboplatin will always be administered by a nurse or doctor experienced in the use of cancer treatment. 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.

Dose

Your dose is dependent on your height and weight, function of your blood (haemopoietic) system and your kidney function. Your doctor will choose the best dose for you. Carboplatin will be diluted before use.

Adults

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

Older people

For elderly patients (over 65 years old), the dosage may need adjusting depending on your physical condition and laboratory evaluation.

Kidney problems

The amount given may vary, according to how well your kidneys are working. If you suffer from kidney problems, your doctor may reduce the dose and may perform frequent blood tests as well as monitoring your kidney function.

Use in children and adolescents

There has not been enough usage of carboplatin in children to allow the recommendation of specific dose.

You may feel sick while you are being treated with carboplatin. Your doctor may give you another medicine to reduce these effects before you are treated with this medicine.

There will be a usual gap of 4 weeks between each dose of carboplatin. Your doctor will want to perform some blood tests each week after giving you this medicine so he/she can decide on the correct next dosage for you.

If you take more Carboplatin than you should

It is unlikely that you will be given too much carboplatin. However in the event that this occurs you may have some problems with your kidneys. If you are worried that too much has been administered or you have any questions about the dose being given, you should talk to the doctor administering your medicine.

If you forget to take Carboplatin

It is very unlikely that you will miss a dose of your medicines, as your doctor will have instructions on when to give you your medicine. If you think you have missed your dose please talk to your doctor.

If you stop taking Carboplatin

If you have any further questions on the use of this product ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you notice any of the following:

- Abnormal bruising, bleeding, or signs of infection such as a sore throat and high temperature.
- Severe itching of the skin (with raised lumps) or swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing or breathing (angio-oedema).
- Stomatitis/mucositis (e.g. sore lips or mouth ulcers).

Very common side effects (may affect more than 1 in 10 people):

- Changes in your red and white blood cells and platelets (myelosuppression). Your doctor may want to monitor you
- Anaemia (a condition in which there is a decreased number of red blood cells which leads to tiredness)
- Increase in the level of urea and enzymes in your blood. Your doctor may want to monitor you
- Slight loss of hearing
- Abnormal liver function test results. Your doctor may want to monitor you
- Increased uric acid levels in your blood which may lead to gout
- Feeling or being sick
- Abdominal pain or cramp
- Unusual feelings of tiredness or weakness
- Decrease in the level of salts in your blood. Your doctor may want to monitor you
- Damage to the kidneys (renal toxicity).

Common side effects (may affect up to 1 in 10 people):

- Unusual bruising or bleeding (haemorrhagic complications)
- Reduced function of your kidneys
- Diarrhoea, constipation, sore lips or mouth ulcers (mucositis)
- Allergic reactions including rash, urticaria, skin reddening, itching, high temperature
- Ringing in the ears (tinnitus), hearing impairment and hearing loss
- Pins and needles (peripheral neuropathy)
- Hair loss
- Feeling unwell
- Decreased serum levels of calcium
- Flu-like syndrome
- Loss or lack of body strength
- Fever
- Interstitial lung disease (a group of lung disorders in which the deep lung tissues become inflamed)

- Decrease bone and tendon reflex.

Uncommon (may affect up to 1 in 100 people)

- Secondary malignancies
- Central nervous symptoms often associated with medicine you may be taking to stop you from feeling or being sick
- Fever and chills without evidence of infection
- Redness, swelling and pain or dead skin around the injection site (injection site reaction)
- Infection
- Unusual weight loss
- Change in blood pressure (hyper or hypotension).

Rare (may affect up to 1 in 10,000 people)

- Feeling unwell with a high temperature due to low levels of white blood cells (febrile neutropenia)
- Life threatening infections and bleeding
- Taste alteration
- Loss of appetite (anorexia)
- Severely impaired liver function, damage or death of liver cells. Your doctor may want to monitor you.
- Temporary visual disturbances including temporary sight loss
- Inflammation of the optic nerve that may cause a complete or partial loss of vision (optic neuritis)
- Haemolytic-uraemic syndrome (a disease characterised by acute renal failure)
- Decreased number of red blood cells (microangiopathic haemolytic anaemia) and a low platelet count)
- Severe allergic reactions (anaphylaxis/anaphylactic reactions)
- Symptoms of a severe allergic reaction include sudden wheeziness or tightness of chest, swelling of the eyelids, face or lips, facial flushing, hypotension, tachycardia, urticaria, dyspnoea, dizziness and anaphylactic shock.

Very rare (may affect up to 1 in 10,000 people)

- Heart failure, blockage in blood vessels of your heart, high blood pressure
- Bleeding in the brain, which may result in a stroke or loss of consciousness
- Scarring of the lungs which causes shortness of breath and/or cough (pulmonary fibrosis).

If you get any side effects, talk to your doctor or nurse. This includes any side effects not listed in this leaflet.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Pharmacovigilance Section
Irish Medicines Board

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Earlsfort Centre
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IRL - Dublin 2
Tel: +353 1 6764971
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Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

5. How to store Carboplatin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and carton after {EXP}. The expiry date refers to the last day of that month.

Unopened vial: Store below 30°C. Keep the vial in the outer carton in order to protect from light.

Diluted product: Chemical and physical in-use stability has been demonstrated after dilution for 24 hours at 2 to 8°C.

From a microbiological point of view however, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 – 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6. Contents of the pack and other information

What Carboplatin contains

- The active substance is carboplatin.
 - One vial of 5 ml contains 50 mg carboplatin.
 - One vial of 15 ml contains 150 mg carboplatin.
 - One vial of 45 ml contains 450 mg carboplatin.
 - One vial of 60 ml contains 600 mg carboplatin.
 - One vial of 100 ml contains 1000 mg carboplatin.
- The other ingredient is water for injection.

What Carboplatin looks like and contents of the pack

Carboplatin is a clear, colourless to pale yellow solution free from particles.

Carboplatin is supplied in type I transparent, flint moulded glass vial containing either 5 ml, 15 ml, 45 ml, 60 ml or 100 ml concentrate for solution for infusion. Vials are closed with grey rubber stoppers and white/blue (60 ml vial only) flip-off aluminium seals.

Pack size:

1 vial.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

Amneal Pharma Europe Limited

70 Sir John Rogerson's Quay,

Dublin 2

Ireland

Manufacturer

Pfizer Service Company BVBA

Hoge Wei 10, B-1930 Zaventem

Belgium

This leaflet was last revised in {07/2013}.

The following information is intended for healthcare professionals only:

This product is for single use only. Any unused infusion solution should be discarded.

Handling and use

The preparation and administration of injectable solutions of cytotoxic agents must be carried out by trained specialist personnel with knowledge of the medicines used, in conditions that guarantee the protection of the environment and, in particular, the protection of the personnel handling the medicines. It requires a preparation area reserved for this purpose. It is forbidden to smoke, eat or drink in this area.

Personnel must be provided with appropriate handling materials, notably long sleeved gowns, protection masks, caps, protective goggles, sterile single-use gloves, protective covers for the work area and collection bags for waste.

Syringes and infusion sets should be assembled carefully to avoid leakage (use of Luer lock fittings is recommended).

Spills and leakages must be wiped up, wearing protective gloves.

Precautions should be taken to avoid exposing staff during pregnancy.

On completion, any exposed surface should be thoroughly cleaned and hands and face washed.

Guidelines for the safe handling of anti-neoplastic agents:

- Carboplatin should be prepared for administration only by professionals who have been trained in the safe use of chemotherapeutic agents
- This should be performed in a designated area.
- Adequate protective gloves, face mask and protective clothes should be worn.
- Precautions should be taken to avoid the drug accidentally coming into contact with the eyes. In the event of contact with the eyes, wash with water and/or saline.
- The cytotoxic preparation should not be handled by pregnant staff.
- Adequate care and precautions should be taken in the disposal of items (syringes, needles, etc...) used to reconstitute cytotoxic drugs. Excess material and body waste may be disposed of by placing in double sealed polyethylene bags and incinerating at a temperature of 1,000°C.
- The work surface should be covered with disposable plastic-backed absorbent paper.
- Use Luer-Lock fittings on all syringes and sets. Large bore needles are recommended to minimise pressure and the possible formation of aerosols. The latter may also be reduced by the use of a venting needle.

Preparation of the solution for infusion

The product must be diluted before use, with glucose solution 50 mg/ml or sodium chloride solution 9 mg/ml, to concentration as low as 0.5 mg/ml. The carboplatin in the vial prior to dilution is at strength 10 mg/ml. The dilutions should be used within

24 hours once diluted with glucose solution 50 mg/ml or sodium chloride solution 9 mg/ml and stored at 2°C to 8°C.

The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.