Package leaflet: Information for the user

Carboplatin 10 mg/ml concentrate for solution for infusion
(50 mg/5 ml, 150 mg/15 ml, 450 mg/45 ml and 600 mg/60 ml)
Carboplatin

The name of this medicine is Carboplatin 10 mg/ml concentrate for solution for infusion but in the rest of the leaflet it will be called '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, please 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

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

What Carboplatin is used for
This medicine 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 have severe problems with your kidneys (creatinine clearance at or below 30 ml/min)
- if you have an imbalance of your blood cells (severe myelosuppression)
- if you have a tumour that bleeds
- Concomitantly with yellow fever vaccine

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 infusion.

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 you are given Carboplatin
If you are pregnant or if there is a chance you may be pregnant

If you are breastfeeding
If you are likely to drink alcohol whilst being treated with this medicine
If you have headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss, tell your doctor.
If you develop extreme tiredness and shortness of breath with decreased number of red blood cells (symptoms of haemolytic anaemia), alone or combined with a low platelet count, abnormal bruising (thrombocytopenia) and kidney disease where you pass little or no urine (symptoms of Haemolytic-uremic syndrome), tell your doctor.
If you have fever (temperature greater than or equal to 38°C), or chills, which could be signs of infection, tell your doctor immediately. You may be at risk of getting an infection of the blood.

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

During treatment with carboplatin you will be given medicines which help reduce a potentially life-threatening complication known as tumour lysis syndrome, which is caused by chemical disturbances in the blood due to the breakdown of dying cancer cells that release their content to the bloodstream.

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.

Other medicines and Carboplatin

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

You must tell your doctor if you are taking any of the following medicines as they may interact with carboplatin.

- other medicines that are known to be toxic to your kidney (e.g. aminoglycosides antibiotics)
- other medicines that are known to damage the hearing or balance functions of the ear (e.g. aminoglycosides antibiotics, furosemide (used to treat heart failure and edema))
- other medicines which decrease the activity of the immune system (e.g. cyclosporine, tacrolimus, sirolimus and other anticancer medicines)
- yellow fever vaccine and other live vaccines
- 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)
- loop diuretics (used to treat hypertension and edema)

Carboplatin with food, drink and 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 treated with 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
You must not be treated with carboplatin during pregnancy unless clearly indicated by your doctor. Animal studies have shown a possible risk of abnormalities in the developing fetus. If you are being

treated with carboplatin whilst pregnant, you should discuss with your doctor the possible risk of effects on your unborn child. Women of childbearing potential must use an effective method of contraception both during and for at least 6 months after treatment with carboplatin. Since carboplatin can cause genetic damage, if pregnancy occurs during treatment with carboplatin, genetic counselling is recommended. Genetic counselling is also recommended for patients wishing to have children after treatment with carboplatin.

Breast-feeding
It is not known whether carboplatin is excreted into the breast milk. Therefore, during treatment with Carboplatin you should discontinue breast-feeding.

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 for at least 3 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 first given carboplatin, especially if you feel dizzy or unsure of yourself.

3. How you are given Carboplatin

This medicine will always be administered by a 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. If you require any further information, ask your doctor or nurse who will administer or has administered the infusion. Your dose will be dependent on your height and weight, function of your blood (haematopoietic) system and your kidney function. Your doctor will choose the best dose for you. The infusion will normally be diluted before use.

Adult
The usual dose is 400 mg/m² of your body surface area (calculated from your 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 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. 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.

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 receive 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, liver, sight and hearing and have low white blood cell count. 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 miss a dose of 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 or nurse.

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

4. Possible side effects

Like all medicines, this medicine can have 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) and you may feel you are going to faint.
- Stomatitis/mucositis (e.g. sore lips or mouth ulcers).

Very common: may affect more than 1 in 10 people
- Suppression of the bone marrow characterised by a severe decrease of white blood cells, which makes infections more likely (leukopenia, neutropenia)
- Reduction in blood platelets, which increases the risk of bruising and bleeding (thrombocytopenia)
- Anaemia (a condition in which there is a decreased number of red blood cells which leads to tiredness)
- Reduced function of your kidneys (Increase in the level of the creatinine and urea in your blood). Your doctor may want to monitor you.
- Slight loss of hearing (high frequency hearing-loss)
- Abnormal liver enzymes levels and abnormal liver function test. Your doctor may want to monitor you.
- Increased uric acid levels in your blood which may lead to gout (hyperuricaemia)
- Feeling or being sick
- Abdominal pain and cramp
  Unusual feelings of tiredness or weakness
- Decrease in the level of salts in your blood (sodium, potassium, calcium, magnesium). Your doctor may want to monitor you.

Common: may affect up to 1 in 10 people
- Unusual bruising or bleeding (haemorrhagic complications)
- 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), weakness, tingling or numbness
- Hair loss
- Feeling unwell
- Flu-like syndrome
- Loss or lack of body strength

- Lung disorders, Scarring and thickening in the lungs with difficulties in breathing, sometimes fatal (interstitial lung disease), difficulty breathing
- Decreased bone and tendon reflex.
- Infections
- Sensory disturbance
- Taste alteration
- Visual disturbances, including temporary sight loss
- Cardiovascular disorder
- Skin disorder
- Itchy skin rash (urticaria)
- Feeling itchy (Pruritus)
- Red rash (rash erythematous)
- Musculoskeletal disorder
- Conditions affecting the urinary and genital tracts (urogenital disorder)
- Increase in the level of the creatinine, bilirubin and uric acid in your blood. Your doctor may want to monitor you

Uncommon: may affect up to 1 in 100 people
- Cancer caused by chemotherapy or radiation (Secondary malignancies)
- Fever and chills without evidence of infection
- Redness, swelling and pain or dead skin around the injection site (injection site reaction)

Rare: may affect up to 1 in 1,000 people
- Feeling unwell with a high temperature due to low levels of white blood cells (febrile neutropenia)
- Loss of appetite (anorexia)
- Severely impaired liver function, damage or death of liver cells. Your doctor may want to monitor you.
- Inflammation of the optic nerve that may cause a complete or partial loss of vision (optic neuritis)
- Severe allergic reactions (anaphylaxis/anaphylactic reactions)
- Symptoms of a severe allergic reactions include sudden wheeziness or tightness of chest, swelling of the eyelids, face or lips, facial flushing, hypotension, tachycardia, urticaria, dyspnoea, dizziness and anaphylactic shock.
- Low levels of sodium in your blood (hyponatraemia)

Very rare: may affect up to 1 in 10,000 people
- Heart failure
- Bleeding in the brain, which may result in a stroke or loss of consciousness
- Sudden blockage of an artery (embolism), high blood pressure, low blood pressure.

Not known side effects (frequency cannot be estimated from the available data):
- Haemolytic uraemic syndrome (a disease characterized by acute renal failure /low urine output /or no urine output, decreased number of red blood cells with extreme tiredness and low platelet count)
- Abnormal bruising or bleeding and signs of infection
- Dehydration
- Sore lips or mouth ulcers (stomatitis)
- muscle cramping, muscle weakness, confusion, visual loss or disturbances, irregular heartbeat, kidney failure or abnormal blood test results (symptoms of tumor lysis syndrome which can be caused by the rapid breakdown of tumour cells) (see section 2).
- A group of symptoms such as headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss (symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder)
- Pancreatitis
- Lung infection.
- Chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome

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 the national reporting system:

UK
Yellow Card Scheme
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

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

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 label and carton after EXP. The expiry date refers to the last day of that month.

Before opening vials: Store below 25°C.
Keep the vial in the outer carton in order to protect from light.

After dilution: Chemical and physical in-use stability has been demonstrated after dilution in Glucose 5% for 96 hours at 2°C to 8°C and 20°C to 25°C.

Chemical and physical in-use stability has been demonstrated after dilution in Sodium Chloride 0.9% for 24 hours at 2°C to 8°C and 8 hours at 20°C to 25°C.

From a microbiological point of view however, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally be no longer than 24 hours at 2ºC to 8ºC, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice any signs of deterioration.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Carboplatin contains

- The active substance is carboplatin. 1 ml of concentrate for solution for infusion contains 10 mg of carboplatin.

  Each 5 ml vial contains 50 mg carboplatin

  Each 15 ml vial contains 150 mg carboplatin

  Each 45 ml vial contains 450 mg carboplatin

  Each 60 ml vial contains 600 mg carboplatin**.**

- The other ingredient is water for injections.

What Carboplatin looks like and contents of the pack

Carboplatin is a clear, colourless to pale yellow solution, free from visible particles. Each milliliter (ml) of concentrate contains 10 milligram (mg) of carboplatin. This medicine is presented in a clear, colourless, type I glass vials with chlorobutyl or bromobutyl rubber closures with green (for 6 ml), blue (for 20 ml), red (for 50 ml) and yellow (for 100 ml) flip-off aluminium overseal. The 5 ml vial contains 50 mg of carboplatin, the 15 ml vial contains 150 mg of carboplatin, the 45 ml vial contains 450 mg of carboplatin and the 60 ml vial contains 600 mg of carboplatin.

The standard vials are available in single pack of 5 ml, 15 ml, 45 ml or 60 ml.

Not all presentations listed above may be marketed.

Marketing Authorisation Holder

For UK:
Fresenius Kabi Limited
Cestrian Court
Eastgate Way,
Runcorn, Cheshire
WA7 1NT
United Kingdom

For IE :
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer
Fresenius Kabi Deutschland GmbH
Pfingstweide 53
61169 Friedberg
Germany

This medicine is authorised in the Member States of the European Economic Area <and in the United Kingdom (Northern Ireland)> under the following names:

Belgium	Carboplatine Fresenius Kabi 10 mg/ml concentraat voor oplossing voor infusie
Czech Republic	Carboplatin Kabi
Germany	Carboplatin Kabi 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Denmark	Carboplatin Fresenius Kabi
Estonia	Carboplatin Kabi 10 mg/ml
Spain	Carboplatino Kabi 10 mg/ml concentrado para solución para perfusión EFG
France	Carboplatine Kabi 10 mg/ml solution à diluer pour perfusion
Hungary	Carboplatin Kabi 10 mg/ml koncentrátum oldatos infúzióhoz
Ireland	Carboplatin 10 mg/ml concentrate for solution for infusion
Iceland	Carboplatin Fresenius Kabi 10 mg/ml innrennslisþykkni, lausn
Latvia	Carboplatin Kabi 10 mg/ml koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Carboplatin Kabi 10 mg/ml koncentratas infuziniam tirpalui
Luxembourg	Carboplatin Kabi 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Malta	Carboplatin 10 mg/ml concentrate for solution for infusion
The Netherlands	Carboplatine Fresenius Kabi 10 mg/ml concentraat voor oplossing voor infusie
Norway	Carboplatin Fresenius Kabi 10 mg/ml konsentrat til infusjonsvæske, oppløsning
Poland	Carboplatin Kabi
Portugal	Carboplatina Kabi
Romania	Carboplatin Kabi 10 mg/ml concentrat pentru soluţie perfuzabilă
Slovak Republic	Carboplatin Kabi 10 mg/ml
United Kingdom	Carboplatin 10 mg/ml concentrate for solution for infusion

This leaflet was last revised in March 2024.

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The following information is intended for healthcare professionals only:

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

Instructions for dilution

Carboplatin may interact with aluminium to form a black precipitate and/or loss of potency. Needles, syringes, catheters or intravenous 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.

The product must be diluted prior to infusion, with 5 % Glucose for Injection or 0.9% Sodium Chloride for Injection, to concentrations as low as 0.5 mg/ml (500 micrograms/ml).

Chemical and physical in-use stability has been demonstrated after dilution in Glucose 5 % for 96 hours at 2°C to 8°C and 20°C to 25°C.

Chemical and physical in-use stability has been demonstrated after dilution in Sodium Chloride 0.9% for 24 hours at 2°C to 8°C and 8 hours at 20°C to 25°C.

From a microbiological point of view however, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally be no longer than 24 hours at 2 ºC to 8 ºC, unless dilution has taken place in controlled and validated aseptic conditions.

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.

Guidelines for the safe handling of anti-neoplastic agents:

1. Carboplatin should be prepared for administration only by professionals who have been trained in the safe use of chemotherapeutic agents
2. This should be performed in a designated area.
3. Adequate protective gloves, face mask and protective clothes should be worn.
4. 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.
5. The cytotoxic preparation should not be handled by pregnant staff.
6. 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 polythene bags and incinerating at a temperature of 1,000°C.
7. The work surface should be covered with disposable plastic-backed absorbent paper.
8. 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.

Disposal

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