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PACKAGE LEAFLET: INFORMATION FOR THE USER

Carboplatin 10 mg/ml Concentrate for Solution for Infusion

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist 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

Carboplatin contains carboplatin, which is a platinum containing compound. It is an anti-cancer agent, which is used either alone or in combination with other drugs.

Carboplatin is used to treat ovarian cancer and lung cancer.

Ask your doctor or nursing staff if you need additional information.

2 What you need to know before you are given Carboplatin

You must not be given Carboplatin
- if you are allergic to carboplatin or any of the other ingredients of this medicine (listed in section 6) or other platinum containing compounds
- if you are breast-feeding
- if you have severe kidney problems
- if you have any bone marrow problems
- if you have a tumour that bleeds
- if you are to receive a yellow fever vaccination or have just received one.

Warnings and precautions
Talk to your doctor before you are given Carboplatin:
- if you have ever suffered an allergic reaction to platinum-containing medicines, such as cisplatin or oxaliplatin (see "You must not be given Carboplatin ")
- if you are elderly (over 65 years old).

Other precautions whilst you are receiving Carboplatin
- Your nervous system function will be checked regularly.
- Your doctor may give you blood or urine tests to check your blood composition, kidney or liver function before, during and after treatment with Carboplatin. This is necessary to continue therapy.
- Your doctor may prescribe anti sickness medicines to prevent nausea and vomiting.
- Good oral hygiene (rinsing the mouth frequently and effective brushing of the teeth with a soft brush 2–3 times daily) may help to prevent developing a sore mouth.
- 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 you have headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss, tell your doctor.
- If you develop extreme tiredness with decreased number of red blood cells, and shortness of breath (haemolytic anaemia), alone or combined with low platelet count, abnormal bruising (thrombocytopenia) and kidney disease where you pass little or no urine (symptoms of haemolytic-uraemic 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.

Other medicines and Carboplatin

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines as some could interact with carboplatin, for example:
- Blood thinning medicines e.g. warfarin. An increased frequency of blood coagulation monitoring is required.
- Live or live-attenuated vaccines (for yellow fever vaccine see section 2 "You must not be given Carboplatin").
- Any drugs which have a side effect of decreasing the number of blood cells, such as **clozapine**, as this effect may become worse when carboplatin is used in combination with these medicines.
- Any drugs which can cause damage to either your kidneys or inner ears e.g.
  - **Capreomycin**, an antibacterial drug used to treat tuberculosis
  - **Aminoglycoside antibacterials**, such as gentamicin, streptomycin
  - **Polymixin antibiotics**, such as colistin
  - **Diuretics** (water tablets) such as bumetanide or furosemide

  Carboplatin may increase the toxic effects of these drugs. The combination of carboplatin with these drugs should be avoided.
- **Phenytoin and fosphenytoin** (used to treat various types of convulsions and seizures), as the level of the medicine in your blood may decrease when used in combination with carboplatin; this may lead to reappearance of seizures. An increase of your phenytoin dose may be necessary.
- Other medicines which decrease the activity of the immune system (e.g. ciclosporin, tacrolimus, sirolimus)
- Chelating drugs (drugs that bind to carboplatin and in this way decrease the effect of carboplatin)

Pregnancy, breast-feeding and fertility
Pregnancy
- Carboplatin should not be given to you if you are pregnant unless clearly indicated by your doctor, due to the possible risk of abnormalities in the developing foetus.
- If you become pregnant or suspect that you may be pregnant during therapy, you must tell your doctor immediately. If you are pregnant or become pregnant during therapy, genetic counselling should be provided.
- **Female patients** should use an effective method of contraception, e.g. the barrier method or condoms, to avoid getting pregnant during treatment, and for 6 months following completion of treatment with carboplatin.
- **Male patients** receiving treatment with carboplatin should also take adequate contraception precautions to ensure that their partner does not become pregnant during treatment, and for 3 months following completion of treatment.

Breast-feeding
- You must not breast-feed during your treatment with carboplatin.

Fertility
Both male and female patients who are considering having a child after the treatment should discuss this with their doctor. Male patients should seek advice on conservation of sperm prior to treatment because of the possibility of irreversible anti-fertility effect.

Driving and using machines
- Carboplatin may cause you to feel or be sick. DO NOT drive or operate machinery until you are sure you are not affected.

3 How Carboplatin is given

- Carboplatin should only be administered by specifically qualified doctors.
- Carboplatin will be diluted and then administered to you by the intravenous (into the vein) route only.
- You will have regular tests performed to monitor your condition.
- There is likely to be about 4 weeks between each dose of carboplatin.

The recommended dose is:
- **Adults**
  400 mg/m^2 given as a single intravenous (into the vein) dose over a period of 15 to 60 minutes.
- **Elderly**
  For elderly patients (over 65 years old), the dosage may need adjusting depending on your physical condition.
- **If you have received treatment previously or have kidney problems**
  Your dosage will be adjusted to suit you.
- **Children and adolescents**
  Carboplatin is not recommended for use in children and adolescents.

If you received more Carboplatin than you should
There is no specific antidote for carboplatin overdosage. If you received too much carboplatin, the doctor will stop the therapy and treat the symptoms.

If administration of Carboplatin is forgotten
Your doctor will decide on what time you will receive this medicine. If you think you have missed a dose, please contact your doctor as soon as possible.

4 Possible side effects

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

If you get any of the following serious side effects, tell your doctor immediately, or seek urgent medical advice:

- Abnormal bruising, bleeding, or signs of infection such as sore throat and high temperature
- Serious allergic reactions: swelling of the lips, face, mouth or neck leading to severe difficulty in breathing; skin rash or hives; swelling of the hands, feet and ankles
- Chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

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

- reduction in the number of platelets associated with bruises and abnormal bleeding (thrombocytopenia), reduction in the number of white blood cells associated with increased infection risk (leukopenia, neutropenia), reduction in the number of red blood cells (anaemia: this may cause tiredness)
- nausea, abdominal pain, vomiting
- toxicity of the kidneys
- unusually high concentration of uric acid in the blood (hyperuricaemia)
- abnormal liver function tests
- changes in blood chemistry (decreased level of blood sodium, blood potassium, blood calcium and blood magnesium)

Common: may affect up to 1 in 10 people

- signs of infection such as fever or sore throat
- bleeding (haemorrhagic) complications
- allergic reactions such as rash, fever with no apparent cause and itch
- a disorder of the nerves (peripheral neuropathy). You may feel a tingling and/or numbness in the fingers, toes, around the mouth or in the throat, which may sometimes occur in association with cramps. These effects are often triggered by exposure to cold e.g. opening a refrigerator or holding a cold drink. You may also have difficulty in performing delicate tasks, such as buttoning clothes
- sensation of tingling, pricking, or numbness of the skin with no apparent physical cause (paraesthesia), decreased tendon reflex
- taste disturbance
- temporary worsening of eyesight or changes to your vision, loss of vision
- hearing loss, hearing problems
- heart disorders
- tightness of the chest or wheezing, tightness of the chest caused by cramping of the respiratory tract muscles (bronchospasm)
- interstitial lung disease (a group of lung disorders in which the deep lung tissue become inflamed)
- diarrhoea, constipation
- sore lips or mouth ulcers (mucous membrane disorders)
- problems with your kidneys or urine
- hair loss (alopecia)
- rash and/or itchy skin
- pain or discomfort in your bones, joints, muscles, or surrounding structures (musculoskeletal disorders)
- extreme tiredness/weekness (asthenia)
- increased level of bilirubin and creatinine in your blood
- increased level of uric acid in your blood which may lead to gout

Not known: frequency cannot be estimated from available data

- lung infection (pneumonia)
- secondary malignancies (cancerous tumour that spreads from its original location to establish secondary tumours in other parts of the body)
- reduced function of the bone marrow; reduction in the number of white blood cells accompanied with fever (febrile neutropenia); disease characterised by abnormal breakdown of red blood cells, failure of the kidney and a reduced number of platelets (haemolytic uraemic syndrome)
- dry mouth, tiredness, and headache due to excessive loss of body water (dehydration), lack of appetite (anorexia)
- decreased sodium levels in the blood (hyponatraemia)
- stroke
- 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)
- heart failure, obstruction in blood vessels (embolism), high blood pressure, low blood pressure
- sore mouth or throat, with inflamed, reddened and swollen lining of the mouth or ulcers in your mouth or throat (stomatitis)
- pancreatitis
- skin disorders such as hives, rash, skin redness (erythema), and itching
- 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).
- injection site reactions such as pain, redness, swelling, nettle rash and dead skin
- general ill feeling (malaise), fever and chills.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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/carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C. Keep the container in the outer carton.

After dilution in 0.9% NaCl solution or 5% glucose solution, storage should be restricted to three hours at room temperature protected from light or 24 hours at 2 °C – 8 °C when carried out under validated aseptic conditions. The storage times relate to the commencement of drug administration.

Only use this product if it is a clear, colourless to faintly yellow solution, free from fibres and particles of foreign matter.
Once opened any unused solution should be discarded using the appropriate precautions. These measures will help protect the environment.

6 Contents of the pack and other information

What Carboplatin contains

- The active substance is carboplatin. Each ml of concentrate contains 10 mg carboplatin.
- The other ingredients are mannitol and water for injections.

What Carboplatin looks like and contents of the pack
Carboplatin concentrate for solution for infusion comes as a clear, colourless to faintly yellow solution, free from particles.

The product is available in packs containing a single 5 ml, 15 ml, 45 ml or 60 ml vial and packs containing 10 vials of 5 ml and 10 vials of 15 ml.

- Each 5 ml vial contains 50 mg of the active ingredient carboplatin.
- Each 15 ml vial contains 150 mg of the active ingredient carboplatin.
- Each 45 ml vial contains 450 mg of the active ingredient carboplatin.
- Each 60 ml vial contains 600 mg of the active ingredient carboplatin.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation holder is Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.
The company responsible for manufacture is Pharmachemie B.V., Haarlem, Holland.

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

Germany:	Carboplatin-Gry 10mg/ml
Italy:	Carboplatino Teva 10 mg/ml
Spain:	Carboplatino Teva 10 mg/ml Concentrado para solución para perfusión
United Kingdom (Northern Ireland):	Carboplatin 10 mg/ml Concentrate for Infusion

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The following information is intended for medical or healthcare professionals only

Carboplatin 10 mg/ml concentrate for solution for infusion

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

Incompatibilities
This medicinal product should not be mixed with other medical products except 5% Glucose for Injection or 0.9% NaCl for Injection.
This product should not be used with aluminium-containing infusion assemblies, syringes and injection needles. The antineoplastic activity can be reduced.

Handling
The solution for infusion must be visually inspected for particulate matter before use.

Guidelines for the safe handling of anti-neoplastic agents:
1. Trained personnel should handle the drug
2. This should be performed in a designated area
3. Adequate protective gloves 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 1000 °C. Liquid waste may be flushed with copious amounts of water.

Dilution
1. The work surface should be covered with disposable plastic-backed absorbent paper.
2. 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.

The product may be diluted with 5% glucose for injection, or 0.9% NaCl for Injection, to concentrations as low as 0.5 mg/ml (500 micrograms/ml).

Method of administration
Carboplatin should be used by the intravenous route only. The solution for infusion is administered by a short term (15 to 60 minutes) infusion.

Special precautions for storage
When diluted as directed, carboplatin solutions should be used within three hours when stored at room temperature (15 °C – 25 °C) protected from light or within 24 hours when stored at 2 °C – 8 °C if dilution is carried out under validated aseptic conditions. Since no antibacterial preservatives are contained in the formulation, it is recommended that any carboplatin solution be discarded three hours after dilution if stored at room temperature protected from light or after 24 hours, if stored under refrigeration. This product is for single dose use only.