Package leaflet: Information for the user

Carbomedac 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, 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 Carbomedac is and what it is used for

The name of your medicine is 'Carbomedac 10 mg/mL concentrate for solution for infusion', but in the rest of the leaflet it will be called 'Carbomedac'.

What Carbomedac is
Carbomedac contains carboplatin, which belongs to a group of medicines known as platinum coordination compounds which are used to treat cancer. You will normally be given this injection in hospital.

What Carbomedac is used for
Carbomedac is used to treat some cancers of the ovary and lung (ovarian cancer of epithelial origin, small-cell lung cancer).

2. What you need to know before you use Carbomedac

Do not use Carbomedac
- 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 medicine that belongs to the group of platinum-containing compounds.
- if you are breast-feeding.
- if you have severe problems with your kidneys.
- if you have an imbalance of your blood cells (severe myelosuppression).
- if you have a tumour that bleeds.
- if you are receiving yellow fever vaccine at the same time.

If any of these apply to you and you have not already discussed this with your doctor or pharmacist, you should do so as soon as possible and before receiving the injection.

Carbomedac is usually given to you in a hospital. Normally you should not handle this medicine. Your doctor will give you the medicine and will carefully and frequently check on you during and after treatment. You will normally have blood tests before you are given each dose.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you receive Carbomedac
- if you have ever suffered an allergic reaction to platinum-containing agents such as oxaliplatin
- if your kidneys are not working properly. In this case your doctor may want to test you more regularly.
- if you are pregnant or if there is a chance you may be pregnant. See section "Pregnancy, breast-feeding and fertility" below.
- if you have headache, confusion, seizures and abnormal vision from blurriness to vision loss.
- if you develop extreme tiredness and shortness of breath with decreased number of red blood cells, alone or combined with a low platelet count, abnormal bruising and kidney disease where you pass little or no urine (symptoms of haemolytic-uremic syndrome).
- if you have a fever (temperature higher than or equal to 38 °C), or chills, which could be signs of infection. In this case, tell your doctor **immediately**. You may be at risk of getting an infection of the blood.
- if you experience visual disturbances
- if you develop abnormal sensations of the skin such as numbness, pins and needles and tingling
- if you have vomiting. In this case your doctor may prescribe medicines for prevention.
- if you experience any hearing difficulties
- if you have recently received or plan to receive any vaccines. During treatment with carboplatin, you should not have a vaccination with "live" or "attenuated" vaccines, such as yellow fever vaccine.

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 pharmacist, you should do so as soon as possible and before receiving the injection.

Other medicines and Carbomedac
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking any of the following medicines as they may interact with Carbomedac:

- when taking medicines which can affect number of cells in your blood.
- when taking medicines which are known to cause kidney toxicity.
- when undergoing treatment with carboplatin, you must not be administered **yellow fever vaccines** (see also "Do not use Carbomedac") because there is an increased risk that you develop yellow fever, which may lead to death.
- any **vaccinations containing live viruses** should not be given to you when you are treated with carboplatin as there is a risk that you develop the disease you are vaccinated against, which may lead to death.
- Carboplatin can reduce the effects of anti-epileptic medicine (e.g. **phenytoin** and **fosphenytoin**).
- Carboplatin may make medicines you take to prevent blood clotting **(anticoagulants)** less effective. Therefore, blood-clotting ability should be checked more often during combined use.
- the simultaneous use of carboplatin with **chelating agents** (agents which can chemically bind to carboplatin) can decrease the antitumor effect of carboplatin.
- Carboplatin toxicity may severely affect the kidneys and hearing ability when given at the same time as medicines that are known to harm the kidneys and ears, e.g. antibiotics called **aminoglycosides** (medicines to prevent/treat certain infections) or **loop diuretics** ("water tablets").
- using carboplatin at the same time as **ciclosporine, tacrolimus** and **sirolimus** (used to suppress the immune system in autoimmune diseases or organ transplantation) can weaken the immune

system which increases the risk for infections. A weakened immune system leads to the risk of increased production of white blood cells.

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 or pharmacist for advice before taking this medicine.

Pregnancy

You must not be treated with Carbomedac during pregnancy unless clearly recommended by your doctor. If you are being treated with Carbomedac while pregnant, you should discuss with your doctor the possible risk of effects on your unborn child.
Women of childbearing potential must use effective contraception during and for at least 6 months after treatment. If pregnancy occurs during treatment with Carbomedac you should speak with a doctor about genetic counselling, since Carbomedac can cause damage to your unborn child.

Breast-feeding

It is unknown whether carboplatin passes into human milk, therefore you must not breastfeed during treatment with Carbomedac. If your doctor considers treatment with Carbomedac absolutely necessary, breast-feeding must be stopped.

Fertility

Carbomedac can cause genetic damage, e.g. mutation in sperm cells. Men treated with Carbomedac are advised not to father a child during and for at least 3 months after treatment. They should seek advice on conservation of sperm prior to treatment because of the possibility of irreversible infertility.

Driving and using machines
Carboplatin may cause nausea, vomiting, vision abnormalities and hearing disorders which may reduce your ability to drive and use machines. Do not drive or use machines if you have any of these symptoms.

3. How to use Carbomedac

Your injection will always be given by your doctor. It is usually given in a drip by slow injection (infusion) in a vein (intravenously) and will usually take between 15 to 60 minutes to be given. If you require any further information, ask your treating doctor.

Your dose will be dependent on your height and your weight and the results of blood tests and kidney function tests. Your doctor will choose the best dose for you. The injection will normally be diluted before use.

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

Kidney problems
If you suffer from kidney problems your doctor may reduce the dose and may perform frequent blood tests as well as monitor your kidney function.

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

There will usually be a gap of four weeks between each dose of Carbomedac. Your doctor will want to perform some blood tests each week after giving you Carbomedac so that he/she can decide on the correct next dosage for you.

If you receive more Carbomedac than you should
It is unlikely that you will be given too much Carbomedac. However, in the event that this occurs you may experience myelosuppression (your bone marrow may not be able to produce new blood cells). This may for example lead to easy bruising. You may also get kidney and liver problems as well as hearing problems. If you are worried that too much has been given or if you have any questions about the dose being given, you should talk to the doctor who is giving you your medicine.

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

If you stop using Carbomedac
Your doctor will normally decide when you should stop treatment with Carbomedac.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Important side effects or symptoms to look out for – and what to do if you are affected

If you think you have any of the following side effects or symptoms, please contact your doctor immediately.

Very common (may affect more than 1 in 10 people)
- reduction in the number of white blood cells (makes infections more likely)
- decrease of red blood cells which can make the skin pale and cause weakness or breathlessness (anaemia)
- reduction in blood platelets (increases the risk of bleeding or bruising)

Common (may affect up to 1 in 10 people)
- infections (possible signs of infections are e.g. sore throat, fever, chills)
- unusual bruising or bleeding (e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels [broken veins])
- allergic reactions including rash, redness, hives, itching, high temperature
- severe allergic reaction (anaphylaxis). This type of reaction is most likely to occur within minutes of receiving Carbomedac. Symptoms of a severe allergic reaction include sudden wheeziness or tightness of the chest, swelling of the eyelids, face or lips, rash, itching and high temperature
- decrease of deep tendon reflexes (reflex of muscles to contract when a muscle tendon is struck)
- abnormal sensations of the skin such as numbness, pins and needles, tingling
- sight problems
- damage to the ear (ototoxicity), e.g. ringing in the ears, hearing loss
- cardiovascular disorder (side effects affecting the circulatory system)
- lung disease
- serious lung condition associated with shortness of breath, difficulties in breathing and/or scarring of the lungs (interstitial lung disease)
- difficulty in breathing or wheezing

Uncommon (may affect up to 1 in 100 people)
- 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

Rare (may affect up to 1 in 1,000 people)
- sight loss
- feeling unwell with a high temperature due to low levels of white blood cells (febrile neutropenia)
- Severe life-threatening infection of the body and blood with impairment of organ functions, commonly called blood poisoning (sepsis/septic shock)
- skin inflammation with skin peeling

Not known (frequency cannot be estimated from the available data)
- stroke
- optic nerve inflammation
- heart failure
- chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- blocking of an artery (embolism)
- redness, swelling and pain or dead skin around the injection site (injection site reactions)
- leakage into the tissue around the place where you received the injection (injection site extravasation)
- 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)
- brain disorder caused by a harmful substance or infection (encephalopathy)• inflammation of the pancreas
- muscle cramping, muscle weakness, confusion, visual loss or disturbances, irregular heartbeat, kidney failure or abnormal blood test results (symptoms of tumour lysis syndrome which can be caused by the rapid breakdown of tumour cells, see section 2)
- diseases of the coronary vessels

Other possible side effects

If you think you have any of the following side effects or symptoms, please contact your doctor as soon as possible.

Very common (may affect more than 1 in 10 people)
- feeling sick (nausea) or being sick (vomiting)
- abdominal pain

Common (may affect up to 1 in 10 people)
- changes in how food tastes
- diarrhoea, constipation, inflammation of mucous membranes
- hair loss
- skin disorder
- musculoskeletal disorder (condition affecting the muscles, joints, tendons and nerves)
- unusual feelings of tiredness or weakness (asthenia)

Uncommon (may affect up to 1 in 100 people)
- muscle pain, joint pain

Not known (frequency cannot be estimated from the available data):
- having not enough water in your body (dehydration)
- loss of appetite
- low blood pressure

- high blood pressure
- inflammation of the lining (mucosa) of the mouth
- hives (skin allergy with development of itchiness and weals)
- rash
- redness of the skin
- itching
- feeling of general discomfort (malaise)

Certain other side effects can only be detected by your doctor, these include:

Very common (may affect more than 1 in 10 people)
- reduced kidney function
- decreased creatinine clearance (the creatinine clearance shows how well your kidneys are working)
- increased levels of urea in your blood
- abnormal liver enzyme levels
- decreases in the levels of salts in your blood, mostly without obvious signs or symptoms

Common (may affect up to 1 in 10 people)
- conditions affecting the urinary and genital tracts
- increased levels of bilirubin in your blood
- increased levels of creatinine in your blood
- increased uric acid levels in the blood which may lead to gout

Very rare (may affect less than 1 in 10,000 people)
- promyelocytic leukaemia (a cancer of the blood and bone marrow) first occurring 6 years after monotherapy and radiation treatment has been reported

Not known (frequency cannot be estimated from the available data)
- reduced liver function, damage or death of liver cells
- cancer caused by chemotherapy
- reduction of blood-cell production in the bone marrow (bone marrow failure)
- acute kidney failure, decreased number of red blood cells [microangiopathic haemolytic anaemia] and low platelet count (haemolytic-uraemic syndrome)
- low blood levels of sodium which can cause confusion, muscle twitching or abnormal heart rhythm (hyponatraemia)
- lung infection

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbomedac

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

You will not be asked to store your medicine. It will be brought to you ready to be administered straight away. There are no special storage conditions for this medicine during administration.

Your doctor or pharmacist will ensure that you do not receive Carbomedac after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Your doctor or pharmacist should ensure that the vial is kept in the outer carton, in order to protect from light, at below 25 °C. It must not be frozen.

When mixed with other solutions the solution should be used immediately or can be stored no longer than 24 hours at 2 °C– 8 °C. Your doctor or pharmacist will ensure that these storage requirements are met.

Do not throw away any medicines via wastewater or household waste. Your doctor or pharmacist will throw away medicines no longer used. These measures will help protect the environment.

6. Contents of the pack and other information

What Carbomedac contains

- The active substance is carboplatin.
- The other ingredient is water for injections.

What Carbomedac looks like and contents of the pack
Carbomedac is a colourless to pale yellow, clear concentrate for solution for infusion.
Each mL of concentrate contains 10 mg carboplatin.

Each 5 mL vial contains 50 mg of carboplatin.
Each 15 mL vial contains 150 mg of carboplatin.
Each 45 mL vial contains 450 mg of carboplatin.
Each 60 mL vial contains 600 mg of carboplatin.
Each 100 mL vial contains 1000 mg of carboplatin.

Packages containing 1 and 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Carbomedac
France	Carboplatine medac 10 mg/mL solution à diluer pour perfusion
Germany	Carbomedac 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Italy	Carboplatino medac
Norway	Carbomedac 10 mg/ml konsentrat til infusjonsvæske, oppløsning
Poland	Carbomedac
Slovak Republic	Carbomedac 10 mg/ml infúzny koncentrát
Slovenia	Karboplatin medac 10 mg/ml koncentrat za raztopino za infundiranje
Sweden	Carbomedac 10 mg/ml koncentrat till infusionsvätska, lösning

This leaflet was last revised in 06/2023.

The following information is intended for healthcare professionals only:

Use/handling

Carboplatin is a mutagenic and potentially carcinogenic substance. Precautions for safe handling of hazardous substances are to be taken for preparation and application. Preparation must be carried out by trained personal wearing adequate protective gloves, disposable gowns and masks.

Carboplatin should not be used with aluminium-containing parts (e.g. infusion assemblies, syringes and injection needles) as carboplatin reacts with aluminium. This can lead to precipitation and thus to reduced antineoplastic activity.

Shelf life after opening the container and preparing the solution for infusion ready-to-use

Chemical and physical in-use stability has been demonstrated in glucose 50 mg/mL (5 %) solution for infusion for 72 hours at room temperature and in sodium chloride 9 mg/mL (0.9 %) solution for infusion for 24 hours at 2 °C to 8 °C, when stored protected from light. However, it is recommended to use solution for infusion reconstituted with sodium chloride 9 mg/mL (0.9 %) solution for infusion immediately after reconstitution.

From a microbiological point of view, 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 not be longer than 24 hours at 2 °C to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Dilution

The product may be diluted with 50 mg/mL (5 %) glucose solution for infusion to concentrations of 0.4 mg/mL to 2 mg/mL or 9 mg/mL (0.9 %) sodium chloride solution for infusion to a concentration of 2 mg/mL.

Disposal

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