

PACKAGE LEAFLET: INFORMATION FOR THE USER

Carboplatin 10mg/ml 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. 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 use Carboplatin
3. How to use Carboplatin
4. Possible side effects
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1. WHAT CARBOPLATIN IS AND WHAT IT IS USED FOR

Carboplatin is an anti-cancer medicine that contains carboplatin in the form of solution for infusion (a solution which may be given as a slow injection by drip).

Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy.

Carboplatin is used in the treatment of some types of lung cancer and advanced ovarian cancer and as adjuvant treatment of testicular germ cells tumors.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CARBOPLATIN

Do not use Carboplatin:

- if you are allergic (hypersensitivity) to carboplatin or to any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney disease;
- if you have fewer blood cells than normal (your doctor will check this);
- if you are pregnant, trying to become pregnant or breast-feeding;
- if you have a tumour that bleeds;
- if you have received a yellow fever vaccination.

Warnings and precautions

Talk to your doctor or pharmacist before using Carboplatin:

- if you have headache, altered mental functioning, 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 (symptoms of 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).
- if you have fever (temperature greater than or equal to 38°C), or chills, which could be signs of infection. You may be at risk of getting an infection of the blood.

Carboplatin should be administered with particular caution in:

- Patients with myelosuppression (decrease in the number of blood cells produced by the bone marrow). The combined treatment with other myelosuppressive drugs (which lead to decrease of blood cells) may require dosage adjustment;
- Patients with hematologic toxicity (lowering of blood cell production);
- Patients with impaired renal function;
- Patients with allergic reactions to platinum-based drugs;
- Patients over 65 years and/or patients previously treated with cisplatin (medication used to treat cancer);
- Patients receiving treatment with a live vaccine;
- Children. In this population a long term audiometric follow-up is recommended.

Carboplatin can react with aluminum, thus should not be used needles, syringes, catheters or IV administration systems containing aluminum in the preparation or administration of carboplatin, in order to avoid any interaction.

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.

Other medicines and Carboplatin

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

The patient's treatment with oral anticoagulants (blood thinning medicine) implies an increased frequency of monitoring of the International Normalised Ratio (INR).

The administration of Carboplatin:

- Is contraindicated in concomitant use with yellow fever vaccine;
- Is not recommended in concomitant use with live-attenuated vaccines

(except yellow fever vaccine) and phenytoin or fosphenytoin (medicines used to treat seizures);

- Should be administered with particular caution in concomitant use with cyclosporine, tacrolimus and sirolimus (medicines that decrease the body's natural defenses against foreign substances), aminoglycosides, vancomycin or capreomycin (antibiotics drugs), phenytoin and fosphenytoin (used to treat various types of convulsions and seizures) and loop diuretics (drugs used to lower blood pressure).

The treatment associated with other myelosuppressive agents (drugs that lead to decrease of blood cells) may require the dose adjustment.

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

The safe use of carboplatin during pregnancy is not known but it is suspected that can cause serious birth defects when administered during pregnancy. Carboplatin is not indicated in pregnancy or in women of childbearing age who may become pregnant, unless the potential benefits to the mother outweigh the possible risks to the foetus.

If the drug is used during pregnancy, or if the patient becomes pregnant while using the drug, the patient should be advised of the potential risk to the fetus. Women of childbearing potential should avoid pregnancy.

Fertility

Most forms of chemotherapy has been associated with reduction of oogenesis (training, development and maturation of the female sex cells in the ovary) and spermatogenesis (sperm formation). There may be decreased function of the gonads (testes and ovaries) originating amenorrhea (absence of menstrual period) or azoospermia (decreased number of sperm in semen) in patients who received anticancer therapy.

Men in the age of sexual maturation treated with carboplatin are advised not to have children during treatment and for 6 months after treatment.

Male gender patients should seek advice on conservation of sperm prior to therapy, since there is the possibility of irreversible infertility due to treatment with carboplatin.

Breast-feeding

It is unknown whether carboplatin is excreted in breast milk therefore breast-feeding is not recommended for mothers under therapy with carboplatin, in order to avoid harmful effects on the nursing infant. If treatment becomes necessary during the lactation period, you should discontinue breast-feeding.

Driving and using machines

There were no studies conducted on the ability to drive and use machines. However, carboplatin can cause nausea, vomiting, vision problems and ototoxicity; therefore, patients should be advised of the potential effect of these events on the ability to drive or operate machinery.

3. HOW TO USE CARBOPLATIN

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The dose that will be given to you will depend on your age, your health, the proper functioning of your kidneys and other medicines you may be taking. The product may be diluted with glucose (sugar solution) or sodium chloride (salt water) before you are given. It will be given to you slowly, usually through

a drip into a vein over 15-60 minutes. You may be given another dose of this medication after 4 weeks.

While you are receiving carboplatin, your doctor will perform blood tests regularly. This is to assess what effect the drug is having and additional doses of carboplatin will be required.

As this medicine will be administered to you while you are in the hospital, it is unlikely that less or more medication would be administered; however, tell your doctor or pharmacist if you have any concerns.

The security measures used in the preparation and administration of substances classified as hazardous should be applied. The preparation should be performed by professionals trained in the safe use, using protective gloves, face mask and protective clothing.

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

Use in children

Use in children and infants is not recommended due to lack of sufficient data in this area.

If you use more Carboplatin than you should

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.

There is no known antidote for overdose with carboplatin.

During clinical trials, there were no cases of overdose. If this occurs, the patient may require appropriate supportive treatment of complications related to myelosuppression, renal and liver failure, kidney failure and impaired auditory function.

In reports for doses up to 1,600 mg/m² patients felt extremely ill, with diarrhea and alopecia.

Use of higher than recommended doses of carboplatin has been associated with loss of vision.

4. POSSIBLE SIDE EFFECTS

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

The frequency of side effects observed is defined as:

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

Common (may affect up to 1 in 10 people)

Uncommon (may affect up to 1 in 100 people)

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

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

Not known (frequency cannot be established from the available data).

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

- Vomiting, nausea, abdominal pain (very common);
- Infections (common);
- Bleeding (common);
- Cardiovascular problems (common);
- Respiratory problems, interstitial lung disease (lung disease with inflammation), bronchospasm (bronchial muscle contraction that causes difficulty breathing) (common);
- Angioedema (swelling) (rare);
- Urticaria, rash, erythema (redness), pruritus (itching) (frequency not known);

- Cerebrovascular accident (CVA) (frequency not known);
- Heart failure (abnormal heartbeat - faster, slower or irregular - or chest pain) (frequency not known);
- Embolism (blockage of blood vessels), hypertension (blood pressure higher than normal), hypotension (blood pressure lower than normal) (frequency not known);
- Paraesthesia (tingling or pins and needles), dysgeusia (altered taste perception and flavor of food) (common);
- Visual disturbances, rare cases of vision loss (common);
- Ototoxicity (at ear level lesion) (common);
- Diarrhoea, constipation (common);
- Hair loss (alopecia), problems with the skin (common);
- Asthenia (weakness) (common);
- Redness, pain or swelling at the injection site, malaise (frequency unknown);
- Chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Other side effects that can be detected during treatment are given below:

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

- Thrombocytopenia (decreased number of platelets in the blood), neutropenia and leucopenia (reduced white blood cell count in the blood), anaemia (decreased numbers of red blood cells);
- A decrease in creatinine clearance;
- Elevated serum levels of: urea, alkaline phosphatase, aspartate aminotransferase, liver function tests;
- Decreased serum levels of sodium, potassium, calcium, magnesium.

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

- Hypersensitivity (allergies);
- Peripheral neuropathy (nerve disease), decreased of osteotendinous reflexes (related to bones and tendons), change in sensitivity;
- Musculoskeletal disorders
- Reproductive or urinary tract disorders;
- Increased blood bilirubin, increased blood creatinine, increased blood uric acid.

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

- temporary sight loss

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

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

Side effects with unknown frequency (cannot be estimated from the available data)

- Reaction to treatment-related to secondary malignancy;
- Bone marrow failure (decrease in the ability to produce blood cells), febrile neutropenia (fever accompanied by low levels of white blood cells), haemolytic uraemic syndrome;
- Dehydration, anorexia (loss of appetite), hyponatremia (sodium levels below normal values);
- Stomatitis (inflammation of the mouth);
- A set 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;
- 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).

Reporting of side effects

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

Store below 25°C. Store in the original package in order to protect from light. Do not freeze.

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. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater 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. Each milliliter (ml) of solution contains 10 milligrams (mg) of carboplatin.
- Each vial of Carboplatin contains 50 mg, 150 mg, 450 mg and 600 mg of carboplatin.
- The other ingredients are water for injections, hydrochloric acid (pH adjustment) and sodium hydroxide (pH adjustment).

What Carboplatin looks like and contents of the pack

Carboplatin is a clear and colorless solution for infusion contained in an amber glass vial closed with a rubber stopper and aluminum cap.

Packaging with 1 vial containing 5 ml, 15 ml, 45 ml or 60 ml of solution for infusion, respectively.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Hikma Farmacêutica (Portugal) S.A.
Estrada do Rio da Mó, 8, 8A e 8B, Fervença, 2705-906 Terrugem SNT, Portugal

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