

CARBOPLATIN ACCORD

Carboplatin Injection 50 mg/5 mL, 150 mg/15 mL and 450 mg/45 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Carboplatin Accord. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given carboplatin against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Carboplatin Accord is used for

This medicine is used to treat:

- ovarian cancer
- cancer of the testes
- some types of lung cancer
- cancer of the brain and/or spinal cord
- cancer of the head and neck
- neuroblastoma (a cancer of the nerves and adrenal glands)
- a type of cancer called sarcoma.

Carboplatin belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. This medicine is classified as a platinum-complex cytotoxic.

It works by killing cancer cells and/or stopping cancer cells from growing and multiplying.

Carboplatin is often used in combination with other medicines to treat cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given Carboplatin Accord

When you must not be given it

You should not be given Carboplatin Accord if you have an allergy to:

- any medicine containing carboplatin
- other platinum-containing compounds such as cisplatin or oxaliplatin
- mannitol

Some of the symptoms of an allergic reaction may include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- dizziness or light-headedness

Females: tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most cytotoxic medicines carboplatin is not recommended for use during pregnancy. Avoid

becoming pregnant by using effective contraception during treatment and up to 6 months after therapy. If there is any need to consider carboplatin during your pregnancy, your doctor or pharmacist will discuss the benefits and risks of using it.

Males: tell your doctor or pharmacist if your partner intends to become pregnant while you are being given carboplatin, or shortly after you have stopped treatment with carboplatin.

Carboplatin may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use some kind of birth control while you are using carboplatin and for at least 12 weeks after you stop treatment. A barrier method of birth control, such as a condom, should be used while you are being given carboplatin and for the first week of this 12 week period. Your doctor will discuss this with you.

Do not breast-feed if you are being treated with this medicine.

It is not known whether carboplatin passes into breast milk and there is a possibility that the breast-fed baby may be affected.

You must not be given this medicine if you have any of the following conditions:

- very low numbers of white blood cells, red blood cells or platelets
- severe kidney problems (your dose may be reduced with some milder conditions).
- severe bleeding

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

If you are not sure whether you should be given this medicine, talk to your doctor.*Before you are given it***Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.****Tell your doctor if you have any of the following medical conditions:**

- kidney problems
- hearing problems
- condition of the blood with a reduced number of red blood cells, white blood cells, or platelets
- bleeding problems or problems with blood clotting
- neurological problems (problems with the nervous system)
- herpes zoster infections (also known as shingles)
- chicken pox (now or recently), or if you have been in recent contact with someone who has chicken pox.

Tell your doctor if you have had previous treatment with cisplatin.**If you have not told your doctor about any of the above, tell them before you are given carboplatin.***Taking other medicines***Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and carboplatin may interfere with each other.

These include:

- other medicines used to treat cancer (such as paclitaxel and cyclophosphamide), radiation

therapy or any other treatment which weakens your immune system

- some antibiotics used to treat serious infections, including aminoglycosides (such as gentamicin, tobramycin or amikacin)
- some vaccines (ask your doctor)
- Phenytoin/fosphenytoin.

These medicines may be affected by carboplatin, or may affect how well it works. You may need different amounts of your medicines, or you may need to take or use different medicines.

Do not have any vaccinations (immunisations) without your doctor's approval while you are being treated with Carboplatin Accord, and for up to 12 months after you stop treatment with it.

Carboplatin may lower your body's resistance to infection and there is a chance that you may get the infection the immunisation is meant to prevent.

In addition, other people living in your household should not take oral polio vaccine (Sabin) since there is a chance they could pass the polio virus on to you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are being given this medicine.

How Carboplatin Accord is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, height, kidney function, blood counts and other chemotherapy medicines you are being given.

Carboplatin may be given alone or in combination with other drugs.

Several courses of carboplatin therapy may be needed depending on your response to treatment.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any unwanted effects have been controlled.

Ask your doctor if you want to know more about the dose of carboplatin you receive.*How it is given*

Carboplatin Accord is diluted in a fluid bag and then given as an infusion (drip) into your veins, over 15 to 60 minutes. It must only be given by a doctor or nurse.

How long it is given

Carboplatin is usually given as a single infusion on one day. This is called one 'cycle' of chemotherapy. A cycle is usually repeated 4 weeks after the previous cycle. Your doctor will decide how many of these cycles you need.

If you receive too much (overdose)

As carboplatin is given to you under the supervision of your doctor, it is very unlikely that you will receive an overdose. However, if you experience any side effects after being given Carboplatin Accord tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

In case of overdose, immediately contact the poisons information center for advice (phone 13 11 26 in Australia).

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Ask your doctor, nurse or pharmacist if you have any concerns.

While you are being given Carboplatin Accord

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given carboplatin.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist you are being given this medicine.

If you become pregnant while you are being treated with this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may want to check your blood pressure and do some blood, hearing and other tests from time to time to check on your progress and detect any unwanted side effects.

Keep follow up appointments with your doctor.

It is important to have your follow-up cycles of carboplatin at the appropriate times to get the best effects from your treatments.

Carboplatin can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- avoid people with infections. Check with your doctor immediately if you think you are getting an infection, or if you get a fever or chills, cough or hoarseness, lower back or side pain, or find it painful or difficult to urinate;
- check with your doctor immediately if you notice any unusual bleeding or bruising,

black stools, blood in urine or stools or pinpoint red spots on your skin;

- be careful when using a regular toothbrush, dental floss or toothpick. Your doctor or nurse may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work done;
- be careful not to cut yourself when you are using sharp objects such as a safety razor or nail cutters;
- avoid contact sports or other situations where you may get bruised or injured.

Carboplatin and its breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen. In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period:

- Flush the toilet twice to dispose of any body fluids and waste
- Wear gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

While you are being given carboplatin your doctor should order regular tests to check the

number of blood cells in your blood. The results of these tests will be used to determine the amount of carboplatin you will be given for your next dose.

Things to be careful of

Be careful driving or operating machinery until you know how carboplatin affects you.

This medicine may cause dizziness, light-headedness, tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

Side Effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are being treated with carboplatin.

Like other medicines, carboplatin may have unwanted side effects, some of which may be serious. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, pharmacist or nurse if you notice any of the following and they worry you:

- mild nausea or vomiting
- diarrhoea or constipation
- weakness, tiredness or fatigue
- sore muscles or joints
- pain or irritation at the injection site
- taste abnormalities.

The above list includes the more common side effects of this

medicine. They are usually mild and short-lived. Temporary loss of hair, particularly that on the scalp is a less common but upsetting side effect of carboplatin and occurs in a small number of patients (about 2 patients per 100 treated). The severity of hair loss will depend on the dose of carboplatin given. It is more common when other anticancer medicines are used together with carboplatin.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- hearing problems
- muscle irritability or cramps
- blurred vision or other visual disturbances
- tingling in the fingers or toes
- flaking or peeling of the skin, rash or itchy rash

The above list includes serious side effects which may require medical attention.

If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:

- signs of an allergic reaction (such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin; dizziness or light-headedness)
- signs of infection, such as fever, chills, sore throat or mouth ulcers
- headaches, changes in mental status (confusion, thinking abnormal, altered consciousness) or seizures
- visual disturbances or loss
- shortness of breath
- rapid breathing or rapid heart rate
- tremor
- unusual bleeding or bruising, blood in urine or stools

- problems with urination e.g. pain or difficulty
- yellowing of the skin or eyeballs
- severe nausea and vomiting
- a feeling of tightness, pressure or heaviness in the chest.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

The benefits and side effects of carboplatin may take some time to occur. Therefore, even after you have finished receiving your carboplatin treatment you should tell your doctor immediately if you notice any of the side effects listed above.

Storage

Carboplatin Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product Description

What it looks like

Carboplatin Accord is a clear colourless solution which will be diluted in a fluid bag and given as an infusion ('drip'). It is available in 3 presentations; 50 mg/5 mL, 150 mg/15 mL and 450 mg/45 mL in single packs.

Ingredients

Active ingredient:
Carboplatin

Inactive ingredient:
Water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Name and Address of the Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

Australian Registration Numbers

50 mg/5 mL: AUST R 215852

150 mg/15 mL: AUST R 215853

450 mg/45 mL: AUST R 215854

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