## CARBOPLATIN ACCORD

## **Consumer Medicine Information (CMI) summary**

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

## 1. Why am I using Carboplatin Accord?

Carboplatin Accord contains the active ingredient carboplatin. Carboplatin Accord is used for the treatment of 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.

For more information, see Section 1. Why am I using Carboplatin Accord? in the full CMI.

## 2. What should I know before I use Carboplatin Accord?

Do not use if you have ever had an allergic reaction to an any medicine containing carboplatin, other platinum-containing compounds (cisplatin or oxaliplatin) or mannitol, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Carboplatin Accord? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with Carboplatin Accord and affect how it works.

See Section 3. What if I am taking other medicines? in the full CMI.

## 4. How do I use Carboplatin Accord?

Carboplatin Accord is an injection and will be given to you by your doctor or nurse.

More instructions can be found in Section 4. How do I use Carboplatin Accord? in the full CMI.

## 5. What should I know while using Carboplatin Accord?

Things you should do	<ul> <li>Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with Carboplatin Accord</li> <li>If you become pregnant while taking this medicine, tell your doctor immediately</li> <li>Keep all your doctor's appointments so that your progress can be checked.</li> <li>Avoid people with infections.</li> <li>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</li> <li>Be careful when using a regular toothbrush, dental floss or toothpick.</li> <li>Be careful not to cut yourself when you are using sharp objects such as a safety razor or nail cutters</li> <li>Avoid contact sports or other situations where you may get bruised or injured</li> </ul>
Driving or using machines	Be careful driving or operating machinery until you know how Carboplatin Accord affects you. This medicine may cause dizziness, light-headedness, tiredness and drowsiness in some people. Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness or light-headedness may be worse.

For more information, see Section <u>5. What should I know while using Carboplatin Accord?</u> in the full CMI.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Some of the common, serious and very serious side effects are included in full below in the CMI. Speak to your doctor if you have any of these side effects and they worry you.

The very serious side effects are:

- 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

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

## CARBOPLATIN ACCORD

**Active ingredient:** carboplatin

## **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Carboplatin Accord. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Carboplatin Accord.

#### Where to find information in this leaflet:

- 1. Why am I using Carboplatin Accord?
- 2. What should I know before I use Carboplatin Accord?
- 3. What if I am taking other medicines?
- 4. How do I use Carboplatin Accord?
- 5. What should I know while using Carboplatin Accord?
- 6. Are there any side effects?
- 7. Product details

## 1. Why am I using Carboplatin Accord?

Carboplatin Accord contains the active ingredient carboplatin. 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 Accord is used for the treatment of:

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

# 2. What should I know before I use Carboplatin Accord?

#### Warnings

#### Do not use Carboplatin Accord if:

- you are allergic to carboplatin or any of the ingredients listed at the end of this leaflet
- always check the ingredients to make sure you can use this medicine

#### Check with your doctor if you have or have had:

 an allergy to any medicine containing carboplatin, other platinum-containing compounds (cisplatin or

- oxaliplatin) or mannitol
- allergies to any other medicines, foods, preservatives or dyes
- very low numbers of white blood cells, red blood cells or platelets
- if you have had previous treatment with cisplatin
- severe kidney problems (your dose may be reduced with some milder conditions)
- hearing problems
- bleeding problems or problems with blood clotting
- neurological problems (problems with the nervous system)
- herpes zoster infections (also known as shingles)
- chicken pox, or if you have been in recent contact with someone who has chicken pox
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

As with many medicines, Carboplatin Accord may harm your developing or breastfeeding baby.

Use an effective method of contraception during treatment with Carboplatin Accord and for up to six months after discontinuation of Carboplatin Accord.

**Males:** tell your doctor if your partner intends to become pregnant while you are using Carboplatin Accord or shortly after you have stopped using Carboplatin Accord.

Use barrier methods of contraception (e.g. condoms) during treatment and for up to 12 weeks after discontinuation of Carboplatin Accord.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

## Some medicines and Carboplatin Accord may interfere with each other.

- 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)
- phenytoin/fosphenytoin
- some vaccines (Do not have any vaccinations 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)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Carboplatin Accord.

## 4. How do I use Carboplatin Accord?

#### How much to use

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.

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.

#### When to use Carboplatin Accord

It is very important that you continue to receive Carboplatin Accord for as long as your doctor prescribes it.

You will have blood tests before you begin treatment with Carboplatin Accord and weekly thereafter.

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 use too much Carboplatin Accord

It is very unlikely that you will receive an overdose of Carboplatin Accord because a trained nurse or doctor will give it. If you think that you have been given too much Carboplatin Accord, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using Carboplatin Accord?

## Things you should do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with Carboplatin Accord
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being treated with 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 taking this medicine, tell your doctor immediately
- Keep all your doctor's appointments so that your progress can be checked. Your doctor will do some tests e.g. blood pressure, blood tests, hearing test at regular intervals to make sure the medicine is working and to prevent any unwanted side effects
- 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

## **Driving or using machines**

Be careful driving or operating machinery until you know how Carboplatin Accord 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.

## Looking after your medicine

The hospital will store Carboplatin Accord under the correct conditions.

## Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Carboplatin Accord that may be left over.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

#### Common side effects

Common side effects		What to do
•	mild nausea or vomiting diarrhoea or constipation weakness, tiredness or fatigue sore muscles or joints pain or irritation at the injection	Speak to your doctor if you have any of these common side effects and
•	site taste abnormalities	they worry you

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.

#### Serious side effects

Serious side effects	What to do
<ul> <li>hearing problems</li> <li>muscle irritability or cramps</li> <li>blurred vision or other visual disturbances</li> <li>tingling in the fingers or toes</li> <li>flaking or peeling of the skin, rash or itchy rash</li> </ul>	Call your doctor straight away

## **Very Serious side effects**

Very Serious side effects	What to do

- 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

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

## 7. Product details

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

#### **What Carboplatin Accord contains**

Active ingredient	carboplatin
(main ingredient)	
Other ingredients	water for injections
(inactive ingredients)	

Do not take this medicine if you are allergic to any of these ingredients.

#### What Carboplatin Accord looks like

Carboplatin Accord is a is a clear colourless solution supplied in a vial in single packs.

(50 mg/5 mL: AUST R 215852, 150 mg/15 mL: AUST R 215853, 450 mg/45 mL: AUST R 215854).

## Who distributes Carboplatin Accord

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

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