

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

CARBOPLATIN 50 mg/5 mL FRESENIUS

CARBOPLATIN 150 mg/15 mL FRESENIUS

CARBOPLATIN 450 mg/45 mL FRESENIUS

CARBOPLATIN 600 mg/60 mL FRESENIUS

Concentrate for solution for infusion

Sugar Free

Read all of this leaflet carefully before you start using CARBOPLATIN FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What CARBOPLATIN FRESENIUS is and what it is used for
2. What you need to know before you are given CARBOPLATIN FRESENIUS
3. How CARBOPLATIN FRESENIUS is given to you
4. Possible side effects
5. How to store CARBOPLATIN FRESENIUS
6. Contents of the pack and other information

1. What CARBOPLATIN FRESENIUS is and what it is used for

It contains the active ingredient carboplatin which belongs to a group of medicines known as platinum coordination compounds, which are used to treat cancer. This medicine is used for the treatment of advanced cancer of the ovary. There is limited evidence to support the use of

CARBOPLATIN FRESENIUS in the treatment of small cell cancer of the lung and cancer of the head and neck.

2. What you need to know before you are given CARBOPLATIN FRESENIUS

Do not use CARBOPLATIN FRESENIUS:

- if you are hypersensitive (allergic) to carboplatin or platinum-containing compounds or any of the other ingredients of CARBOPLATIN FRESENIUS (listed in section 6).
- if you have severe problems with your kidneys (your doctor will check of your creatinine clearance level at or below 20 mL /min, by conducted medical tests).
- if you have an imbalance of your blood cells (severe myelosuppression).
- if you have a tumour that bleeds.
- if you plan to receive a yellow fever vaccination or have just received one.
- if you are pregnant or breastfeeding.

Warnings and precautions

Only experienced doctor or healthcare provider in cancer therapy should provide you with treatment.

Your doctor will conduct regular blood tests, as well as kidney and liver tests.

Special care should be taken with CARBOPLATIN FRESENIUS:

- CARBOPLATIN FRESENIUS should not be repeated more frequently than monthly.
Levels of your red and white blood cells and platelets should be monitored during treatment frequently.

Tell your doctor or healthcare worker:

- if you develop extreme tiredness and shortness of breath with decreased number of red blood cells, (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 kidney or liver problems. Your doctor will want to monitor you more regularly.
- if you have ever suffered an allergic reaction to platinum-containing medicines.
- if you are elderly (over 65 years old).
- if you have been treated with cisplatin or similar anti-cancer medicines in the past, CARBOPLATIN FRESENIUS may cause abnormalities in your nervous system, such as pins and needles or hearing and vision problems. Your doctor may regularly assess you.
- if you have headache, altered mental functioning, seizures (fits) and abnormal vision (from blurriness to vision loss).
- if you have been administered with a vaccine.
- 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.

During treatment with carboplatin, you may experience 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.

Children

Safety and effectiveness of CARBOPLATIN FRESENIUS administration in children are not proven.

Other medicines and CARBOPLATIN FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- live or live-attenuated vaccines (such as yellow fever vaccine).
- phenytoin and fosphenytoin (used to treat various types of convulsions and seizures), at the same time as CARBOPLATIN FRESENIUS, may increase the risk of a seizure.

- other medicines which decrease the activity of the immune system (e.g. cyclosporin, tacrolimus, sirolimus).
- some water tablets (diuretics), at the same time as CARBOPLATIN FRESENIUS may increase the risk of kidney or hearing problems.
- medicines which can reduce the number of cells in your blood, at the same time as CARBOPLATIN FRESENIUS, may require changes to the dosage and frequency of your CARBOPLATIN FRESENIUS treatment.
- some antibiotics called aminoglycosides, at the same time as CARBOPLATIN FRESENIUS, may increase the risk of kidney problems.
- blood thinning medicines e.g. warfarin, at the same time as CARBOPLATIN FRESENIUS may require an increase in frequency of blood coagulation monitoring.

Needles, syringes, catheters or IV administration sets that contain aluminium parts which may come into contact with CARBOPLATIN FRESENIUS, should not be used for the preparation or administration of the medicine.

CARBOPLATIN FRESENIUS with food, drink and alcohol

No known interactions.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Pregnancy

Due to the possible risk of birth defects, female patients of childbearing potential should take contraceptive measures before and during treatment with CARBOPLATIN FRESENIUS.

Breastfeeding

You must not breastfeed while you are treated with CARBOPLATIN FRESENIUS

Fertility

Men treated with this medicine are advised not to father a child during, and up to 6 months after treatment. Advice on conservation of sperm should be sought prior to treatment because of the possibility of irreversible infertility. Treatment with CARBOPLATIN FRESENIUS may temporarily or permanently reduce fertility in men and women.

Driving and using machines

Do not drive or use machines if you experience any side effect which may lessen your ability to do so such as nausea, vomiting, worsening of eyesight, or changes to your vision and hearing.

It is not always possible to predict to what extent CARBOPLATIN FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CARBOPLATIN FRESENIUS affects them.

CARBOPLATIN FRESENIUS contains water for injection

3. How CARBOPLATIN FRESENIUS is given to you

Do not share medicines prescribed for you with any other person

You will not be expected to give yourself CARBOPLATIN FRESENIUS. It will be given to you by a person who is qualified to do so.

This medicine will be given by infusion (drip) into a vein over 15-60 minutes.

Recommended Dose

Your doctor will work out the correct dose of CARBOPLATIN FRESENIUS for you and how often it must be given.

The recommended dose will depend on your medical condition, your size and how well your kidneys are working.

Your doctor will tell how well your kidneys are working using blood or urine samples. You will have regular blood tests after your dose of CARBOPLATIN FRESENIUS.

You may also have checks for nerve damage and hearing loss. There is likely to be about 4 weeks between each dose of CARBOPLATIN FRESENIUS. The infusion will normally be diluted before use.

Dose for Adults:

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

Dose for Elderly:

The usual adult doses may be used although the doctor may choose to use a different dose

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Dose if you have kidney problems:

The amount given may vary, according to how well your kidneys are working.

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

Children and adolescents

There has not been enough usage of CARBOPLATIN FRESENIUS in children to allow the recommendation of specific dose.

If you use more CARBOPLATIN FRESENIUS than you should

Since a healthcare provider will administer CARBOPLATIN FRESENIUS, he / she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

Symptoms of overdosage may relate to kidney, liver, hearing and vision problems.

Myelosuppression (decreased blood cells) may also be increased.

If you forget to use CARBOPLATIN FRESENIUS

Since a healthcare provider will administer CARBOPLATIN FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

CARBOPLATIN FRESENIUS can have side effects.

Not all side effects reported for CARBOPLATIN FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking CARBOPLATIN FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop using CARBOPLATIN FRESENIUS and tell your doctor immediately:

- abnormal bruising, bleeding, or signs of infection such as a sore throat and high temperature
- severe allergic reaction (anaphylaxis/anaphylactic reactions) - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint and you may experience chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome
- haemolytic-uraemic syndrome (a disease characterised by acute kidney failure), decreased urination or blood in the urine

- suppression of the bone marrow characterised by a severe decrease of white blood cells, which makes infections more likely (leukopenia, neutropenia)
- reduction in blood platelets, which increases the risk of bruising and bleeding (thrombocytopenia)
- unusual bruising or bleeding (haemorrhagic complications)
- heart failure
- bleeding in the brain, which may result in a stroke or loss of consciousness
- sudden blockage of an artery (embolism)
- Sore lips or mouth ulcers (stomatitis)

These are all very serious side effects. If you have them, you may have had a serious reaction to CARBOPLATIN FRESENIUS. You may need urgent medical attention or hospitalization.

Some side effects could be serious. Tell your doctor straight away if you notice any of the following symptoms:

- A side effect called tumour lysis syndrome, which can be caused by the rapid breakdown of tumour cells and may cause irregular heartbeat, kidney failure or abnormal blood test results.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- anaemia (a condition in which there is a decreased number of red blood cells which lead to tiredness)
- abnormal liver enzymes levels and abnormal liver function test.
- increased uric acid levels in your blood
- decrease in the level of salts in your blood (sodium, potassium, calcium, magnesium).
- hearing loss or ear imbalance or ringing in the ears
- pins and needles (peripheral neuropathy), weakness, tingling or numbness
- difficulty breathing

- cough with phlegm or pus, fever, chills and difficulty breathing (pneumonia)
- musculoskeletal disorder (muscle or bone pain or problems)
- conditions affecting the urinary and genital tracts (urogenital disorder)
- upper abdominal pain, nausea and vomiting (pancreatitis)
- cancer caused by chemotherapy or radiation (secondary malignancies)
- dead skin around the injection site (injection site necrosis)
- feeling unwell with a high temperature due to low levels of white blood cells (febrile neutropenia)
- high blood pressure, low blood pressure

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- feeling or being sick, diarrhoea, constipation, abdominal pain and cramp
- unusual feelings of tiredness or weakness
- hair loss
- burning or prickling sensation
- decreased bone and tendon reflexes
- taste alteration
- visual disturbances, including temporary sight loss
- skin disorder
- interstitial lung disease (a group of lung disorders in which the deep lung tissues become inflamed)

Frequency of side effects not known:

- scarring of the lungs which causes shortness of breath and/or cough (pulmonary fibrosis)
- dry mouth, tiredness, and headache due to excessive loss of body water, dehydration
- loss of appetite (anorexia)

- feeling unwell with high temperature due to low levels of white blood cells (febrile neutropenia)
- a group of symptoms such as headache, altered mental functioning, seizures and abnormal vision (from blurriness to vision loss). These are symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder
- redness, swelling and pain around the injection site (injection site reaction)
- itchy skin rash (urticaria), feeling itchy (pruritus), red rash (rash, erythematous)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CARBOPLATIN FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store CARBOPLATIN FRESENIUS

Store all medicines out of reach of children.

Hospital staff will store your medicine safely:

- Before opening vials: Store below 25 °C. Keep vial in the outer carton to protect it from light.
- After dilution:

Chemical and physical in-use stability has been demonstrated after dilution in Glucose 5 %

for 96 hours at 2 °C to 8 °C and 20 °C to 25 °C.

Chemical and physical in-use stability has been demonstrated after dilution in Sodium Chloride 0,9 % for 24 hours at 2 °C to 8 °C and 8 hours at 20 °C to 25 °C.

- Store in the original container.
- Keep the container in the outer carton.
- Keep the container tightly closed.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CARBOPLATIN FRESENIUS contains

The active substance is carboplatin.

One mL of concentrate for solution for infusion contains 10 mg of carboplatin.

CARBOPLATIN FRESENIUS is available as:

CARBOPLATIN 50 mg/5 mL FRESENIUS: Each 5 mL vial contains 50 mg carboplatin

CARBOPLATIN 150 mg/15 mL FRESENIUS: Each 15 mL vial contains 150 mg carboplatin

CARBOPLATIN 450 mg/45 mL FRESENIUS: Each 45 mL vial contains 450 mg carboplatin

CARBOPLATIN 600 mg/60 mL FRESENIUS: Each 60 mL vial contains 600 mg carboplatin

The other ingredient is water for injection

What CARBOPLATIN FRESENIUS looks like and contents of the pack

This medicine is a concentrate for solution for infusion. It is a clear, colourless concentrate for solution for infusion free from visible particles.

CARBOPLATIN 50 mg/5 mL FRESENIUS: Type I, clear, colourless tubular glass vial with a Chlorobutyl, flurotec coated or Bromobutyl, Omniflex Plus coated grey rubber closure with an aluminium flip-off overseal with green flip.

CARBOPLATIN 150 mg/15 mL FRESENIUS: Type I, clear, colourless tubular glass vial with a Chlorobutyl, flurotec coated or Bromobutyl, Omniflex Plus coated grey rubber closure with an aluminium flip–off overseal with blue flip.

CARBOPLATIN 450 mg/45 mL FRESENIUS: Type I, clear, colourless tubular glass vial with a Chlorobutyl, flurotec coated or Bromobutyl, Omniflex Plus coated grey rubber closure with an aluminium flip–off overseal with red flip.

CARBOPLATIN 600 mg/60 mL FRESENIUS: Type I, clear, colourless tubular glass vial with a Chlorobutyl, flurotec coated or Bromobutyl, Omniflex Plus coated grey rubber closure with an aluminium flip–off overseal with yellow flip.

Holder of Certificate of Registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

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This leaflet was revised in

15 October 2024

Registration number

CARBOPLATIN 50 mg/5 mL FRESENIUS : 48/26/0254

CARBOPLATIN 150 mg/15 mL FRESENIUS: 48/26/0255

CARBOPLATIN 450 mg/45 mL FRESENIUS: 48/26/0256

CARBOPLATIN 600 mg/60 mL FRESENIUS: 48/26/0257

Access to the corresponding Professional Information

The professional information will be printed and packed with the product.