

Applicant: Ruby Pharmaceuticals (Pty) Ltd

Proprietary Name: SPALCARB 50 / 150 / 450

API & Dosage Form & Strength(s): Carboplatin / concentrate for solution for infusion / 10 mg / ml

Date: 13 December 2022

Ver: Vf

1.3.2 PATIENT INFORMATION LEAFLET



SCHEDULING STATUS: S4

SPALCARB 50 (Concentrate for solution for infusion)

SPALCARB 100 (Concentrate for solution for infusion)

SPALCARB 450 (Concentrate for solution for infusion)

Carboplatin

Sugar free

Read all of this leaflet carefully before you are given SPALCARB

- 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 **SPALCARB** is and what it is used for
2. What you need to know before you use **SPALCARB**
3. How to use **SPALCARB**
4. Possible side effects
5. How to store **SPALCARB**
6. Contents of the pack and other information

1. What SPALCARB is and what it is used for

SPALCARB belongs to a group of medicines known as alkylating agents. It has anti-tumour properties and it is used to treat patients with advanced or recurrent ovarian cancer. There is limited evidence to support the use of **SPALCARB** in small lung cancer and cancer of the head and neck.

2. What you need to know before you receive SPALCARB

Do not use SPALCARB Intravenous Infusion



- if you are allergic to carboplatin or to any of the ingredients of this medicine (listed in section 6)
- if you have had hypersensitivity to similar platinum containing medicines in the past
- if you have severe kidney disease
- if you have fewer blood cells than normal (your doctor will check this with a blood test)
- if you have a tumour that bleeds
- if you are pregnant and breast feeding

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using **SPALCARB**

- if you have mild renal disease. Your doctor will want to monitor you more regularly.
- if you are elderly (over 65 years old).
- if you have been treated with cisplatin or similar anti-cancer medicines in the past, carboplatin 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 and abnormal vision (from blurriness to vision loss).
- 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 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 **SPALCARB** 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.

Children

Safety and efficacy have not been established.

Other medicines and SPALCARB

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

- medicines which can reduce the number of cells in your blood, at the same time as carboplatin, may require changes to the dosage and frequency of your carboplatin treatment
- some antibiotics called aminoglycosides, vancomycin or capreomycin, at the same time as carboplatin, may increase the risk of kidney or hearing problems
- some water tablets (diuretics), at the same time as carboplatin, may increase the risk of kidney or hearing problems
- live or live-attenuated vaccines (for yellow fever vaccine, Do not use SPALCARB Intravenous Infusion)
- blood thinning medicines e.g. warfarin, at the same time as carboplatin, may require an increase in frequency of blood coagulation monitoring
- phenytoin and fosphenytoin (used to treat various types of convulsions and seizures), at the same time as carboplatin, may increase the risk of a seizure
- other medicines which decrease the activity of the immune system (e.g. ciclosporin, tacrolimus, sirolimus)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being administered **SPALCARB**.



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

Men treated with **SPALCARB** 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 **SPALCARB** may temporarily or permanently reduce fertility in men and women. Tell your doctor if you have concerns.

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 **SPALCARB** 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 **SPALCARB** affects them.

3. How SPALCARB is given

SPALCARB is given by intravenous injection. The infusion bags must be covered with aluminium foil to protect the solution from light.

SPALCARB should be administered under the supervision of a qualified doctor experienced in the use of antineoplastic therapy.

Dosing

The exact amount of medicine has been carefully worked out by your doctor.

SPALCARB is often given together with certain other medicines, in which case your doctor may adjust the dosage. Your doctor may also adjust the dosage if you are an older patient.



SPALCARB commonly causes nausea and vomiting. However, it is important that you continue to receive the medicine, even if you begin to feel ill. Ask your doctor, nurse or pharmacist for ways to lessen these effects, especially if they are severe.

If you use more **SPALCARB** than you should

Since a health care provider will administer **SPALCARB**, he / she will control the dosage.

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

If you forget to use **SPALCARB**

Since a health care provider will administer **SPALCARB**, it is unlikely that the dose will be missed.

4. Possible side effects

SPALCARB can have side effects.

Not all side effects reported for **SPALCARB** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **SPALCARB**, please consult your health care provider for advice.

If any of the following happens, stop using **SPALCARB** 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
- haemolytic-uraemic syndrome (a disease characterised by acute kidney failure), decreased urination or blood in the urine



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

Tell your doctor immediately if you notice any of the following:

- 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.

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects:

Frequent:

- tiredness, shortness of breath and paleness caused by anaemia (a condition in which there is a decreased number of red blood cells)
- feeling sick (nausea) or being sick (vomiting)
- stomach pain and cramp
- signs of infection such as fever or sore throat
- flu-like symptoms
- symptoms of severe allergic reaction include sudden wheeziness or tightness of chest, swelling of the eyelids, face or lips, facial flushing, low blood pressure, rapid heart beat, hives, shortness of breath, dizziness and anaphylactic shock
- tingling or numbness in your hands, feet, arms or legs
- burning or prickling sensation
- decreased tendon reflex
- taste disturbance or loss of taste
- temporary worsening of eyesight or changes to your vision
- ringing in the ears or changes in your hearing



- heart disorders
- tightness of the chest or wheezing
- interstitial lung disease (a group of lung disorders in which the deep lung tissues become inflamed)
- diarrhoea or constipation
- sore lips or mouth ulcers (mucous membrane disorders)
- hair loss
- rash and/or itchy skin
- pain or discomfort in your bones, joints, muscles, or surrounding structures (musculoskeletal disorder)
- problems with your kidneys or urine
- extreme tiredness/weakness (asthenia)

Frequency unknown

- temporary sight loss
- scarring of the lungs which causes shortness of breath and/or cough (pulmonary fibrosis)
- cancers caused by treatment with **SPALCARB** (secondary malignancies)
- 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
- dry mouth, tiredness, and headache due to excessive loss of body water (dehydration)
- loss of appetite, anorexia



- pancreatitis
- stroke (sudden numbness or weakness in the face, arm, or leg, especially on one side of the body)
- severely impaired liver function, damage or death of liver cells
- heart failure
- obstruction in a blood vessel (embolism and veno-occlusive disease), swelling or tenderness of leg/arm
- changes in blood pressure (hypertension or hypotension)
- skin disorders such as hives, rash, skin redness (erythema), and itching
- swelling or soreness where the injection was given
- fewer red blood cells due to their excessive breakdown (haemolytic anaemia)
- mental changes (encephalopathy)
- lung infection
- 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)

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

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 to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **SPALCARB**

5. How to store SPALCARB



Store all medicines out of reach of children.

Store at or below 25 °C

Store in the original package to protect from light.

Contents of the pack and other information

What SPALCARB contains

- The active substance is carboplatin

The other ingredients are:

- water for injection

What SPALCARB looks like and contents of the pack

SPALCARB is a clear, colourless to slightly pale yellow solution free from visible particles and is packed in Amber Type I glass vial with 20mm laminated chlorobutyl rubber stopper and sealed with 20 mm light blue coloured flip-off seal in unit carton

Holder of Certificate of Registration

Ruby Pharmaceuticals (Pty) Ltd

Unit 1, 96 Hartley Road

Durban, 4091

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