Applicant: Teva Pharmaceuticals (Pty) Ltd
Product name: CARBOSIN 150 / 450 / 600
Dosage form & strength: Each 15 ml, 45 ml or 60 ml single dose glass vial contains 150 mg, 450 mg or 600 mg carboplatin, respectively.
Registration Numbers: Z/26/260 ; Z/26/261 ; Z/26/262 ; A39/26/0170

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CARBOSIN 50 Solution for injection contains 50 mg carboplatin

CARBOSIN 150 Solution for injection contains 150 mg carboplatin

CARBOSIN 450 Solution for injection contains 450 mg carboplatin

CARBOSIN 600 Solution for injection contains 600 mg carboplatin

Read all of this leaflet carefully before you receive CARBOSIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CARBOSIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT CARBOSIN CONTAINS:

Active ingredients:

CARBOSIN 50 contains 50 mg carboplatin (10 mg/ml) as the active ingredient.

CARBOSIN 150 contains 150 mg carboplatin (10 mg/ml) as the active ingredient.

CARBOSIN 450 contains 450 mg carboplatin (10 mg/ml) as the active ingredient.

CARBOSIN 600 contains 600 mg carboplatin (10 mg/ml) as the active ingredient.

Inactive ingredients:

Mannitol and water for injection.

2. WHAT CARBOSIN IS USED FOR:

Carboplatin 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 CARBOSIN in small cell lung cancer and cancer of the head and neck.

CARBOSIN is to be administered only by or under the immediate supervision of your doctor.

3. BEFORE RECEIVING CARBOSIN:

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

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

The following should be considered before you start treatment with CARBOSIN:

Allergies:

Tell your doctor if you have ever had any unusual or allergic reaction to carboplatin, cisplatin, or any other platinum-containing substance.

Pregnancy:

There is a chance that this medicine may cause birth defects if either the male or female is taking it at the time of conception or if it is taken during pregnancy. Carboplatin causes toxic or harmful effects and birth defects in rats. CARBOSIN should therefore be avoided during pregnancy.

It is best to use some kind of birth control while you are receiving CARBOSIN and also for a 3-month period after stopping treatment.

Breastfeeding:

Because carboplatin may cause serious side-effects, breastfeeding is not recommended while you are receiving it.

Children:

Studies on this medicine have been done only in adult patients and as there is no dosage recommendation for children, the use of CARBOSIN is not recommended in children.

Older patients:

Some side effects of this medicine may be more likely to occur in older patients. Your doctor may decide to adjust or lower the dosage if you are an older patient.

Other medicines:

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your doctor if you are taking any other medication or if you have been treated with other cancer medicines.

Other medical problems:

The presence of other medical problems may affect the use of CARBOSIN. Make sure you tell your doctor if you have any other medical problems, especially kidney disease.

Other Precautions:

It is very important that your doctor checks your progress at regular visits to make sure that this medicine is working properly and to check for unwanted effects. It is also essential that examinations of blood and neurological checks are made regularly during treatment with CARBOSIN.

While you are being treated with CARBOSIN, and after you stop treatment with it, do not have any vaccinations without your doctor's approval.

CARBOSIN can lower the number of white blood cells in your blood temporarily, increasing the chance of getting infection. It can lower the number of platelets, which are necessary for proper blood clotting. If this occurs, there are certain precautions you can take, especially when your blood count is low, to reduce the risk of infection or bleeding:

- If you can, avoid people with infections;

- Check with your doctor immediately if you notice any unusual bleeding or bruising; black tarry stools; blood in the urine; or pinpoint red spots on your skin;
- Be careful when using a regular toothbrush, dental floss or toothpick;
- Wash your hands before touching your eyes or the inside of your nose;
- Be careful not to cut yourself when you are using sharp objects;
- Avoid contact sports or other situations where bruising or injury could occur.

4. HOW TO RECEIVE CARBOSIN:

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

CARBOSIN should be administered under the supervision of a qualified physician experienced in the use of antineoplastic therapy.

Dosing:

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

CARBOSIN 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.

CARBOSIN 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.

Do not share medicines prescribed for you with any other person.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

5. POSSIBLE SIDE EFFECTS:

Along with its needed effects, CARBOSIN can sometimes cause unwanted effects such as blood problems, ear and kidney problems, and other side-effects. These are described below.

Blood disorders:

Frequent: Abnormally small number of red blood cells, white blood cells or platelets in the blood.

Gastrointestinal disorders:

Frequent: Nausea and vomiting are common.

Nervous system disorders:

*Less frequent***:** Numbness or tingling in fingers or toes.

Ear disorders:

Less frequent: Ringing in the ears.

Kidney disorders:

Frequent: Decrease in serum electrolytes, including sodium, potassium, magnesium and calcium.

Allergic reactions:

Less frequent: Skin rash or itching; wheezing.

Liver disorders:

Less frequent: Abnormal liver function tests have been reported.

General disorders and administration site conditions:

Frequent: Pain at place of injection; unusual tiredness or weakness.

Less frequent: Loss of hair; sores in the mouth and on lips.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF CARBOSIN:

Store away from heat and direct light. Discard any unused portion.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

7. PRESENTATION OF CARBOSIN:

CARBOSIN 50: 5 ml single dose amber glass vial containing 50 mg/5 ml carboplatin.

CARBOSIN 150: 15 ml single dose amber glass vial containing 150 mg/15 ml carboplatin.

CARBOSIN 450: 45 ml or 50 ml single dose amber glass vial containing 450 mg/45 ml carboplatin.

CARBOSIN 600: 100 ml single dose amber glass vial containing 600 mg/60 ml carboplatin.

8. IDENTIFICATION OF CARBOSIN:

A clear, colourless to faintly yellow solution, free from fibres and particles of foreign matter.

9. REGISTRATION NUMBERS:

CARBOSIN 50:	Z/26/260
CARBOSIN 150:	Z/26/261
CARBOSIN 450:	Z/26/262
CARBOSIN 600:	A39/26/0170

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

05 February 2016

Botswana	**Namibia**
CARBOSIN 150: BOT0400614 CARBOSIN 450: BOT0400615 S2	CARBOSIN 150: 04/26/1206 CARBOSIN 450: 04/26/1207 NS2