

**Package leaflet: Information for the patient**  
**Carboplatin Cipla 10mg/ml concentrate**  
**for solution for infusion**  
carboplatin

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or nurse.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

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

**1. What Carboplatin Cipla is and what it is used for**

This medicine contains carboplatin, which belongs to a group of medicines known as platinum coordination compounds, which are used to treat cancer.

Carboplatin Cipla is used against advanced cancer of the ovary and small cell cancer of the lung.

**2. What you need to know before you are given Carboplatin Cipla**

**Do not use Carboplatin Cipla**

- If you are allergic to carboplatin or to any of the ingredients of this medicine (listed in section 6)
- if you are breast feeding
- If you are allergic to another medicine that belongs to the group of platinum containing compound.
- If you have severe kidney problems
- If you have a condition in which the bone marrow cannot make enough blood cells (sever myelosuppression)
- If you have bleeding tumours
- If you are due to receive, or have recently received, yellow fever vaccine.

If any of the above applies to you and you have not already discussed this with your doctor or nurse, you should do so as soon as possible and before receiving an infusion.

Carboplatin Cipla is usually given to patients in the hospital. Normally you should not handle this medicine. Your doctor or nurse will give you the medicine and will carefully and frequently monitor you during and after treatment. You will normally have blood tests before each infusion.

**Warnings and precautions**

Talk to your doctor or pharmacist or nurse before receiving Carboplatin Cipla:

- If you have kidney problems

Your doctor will want to monitor you more regularly if your kidneys are not working properly.

If any of the above applies to you and you have not already discussed this with your doctor or nurse, you should do so as soon as possible and before receiving an infusion.

**Children**

The safety and effectiveness of carboplatin treatment in children has not been proven. Children are at greater risk of developing hearing loss following treatment with carboplatin. Their hearing should be regularly monitored on a long-term basis

**Other medicines and Carboplatin Cipla:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It's especially important that you tell your doctor if you are taking any of the following medicines as they may interact with Carboplatin Cipla.

- Yellow fever vaccine (see section “Do not use Carboplatin Cipla”) and other attenuated vaccines. There is a risk that you will become seriously ill from the vaccine.
- Other medicines that are known to affect blood cell formation in the bone marrow.
- Antibiotics called aminoglycosides, vancomycin or capreomycin. These medicines can increase the risk of side effects to your kidneys or your hearing.
- Diuretics used to treat high blood pressure. These medicines can increase the risk of side effects to your kidneys or your hearing.
- Chelating agents (substances binding to carboplatin thereby decreasing the effect of carboplatin)
- Phenytoin, fosphenytoin (used to treat epilepsy). The effect of phenytoin and fosphenytoin may be reduced and the side effects of carboplatin may increase.
- Anticoagulants (medicine to thin the blood), such as warfarin. You might need to have blood tests more often.
- Medicines used to reduce the activity of the immune system, such as cyclosporin, 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, ask your doctor for advice before taking this medicine.

**Pregnancy**

You must not be treated with carboplatin during pregnancy unless it's absolutely necessary, since it can cause damage to the developing fetus.

Women of child bearing potential must use an effective method of contraception during treatment.

Men are recommended not to father a child during treatment and up to 6 month afterwards.

**Breast – feeding**

It is not known whether carboplatin is excreted into the breast milk. Therefore, during treatment with carboplatin you must discontinue breast-feeding.

**Fertility**

If you are thinking about having children after the treatment with Carboplatin Cipla you should discuss this with your doctor as carboplatin may cause infertility.

**Driving and using machines**

You alone are responsible to decide if you are in condition to drive a motor vehicle or perform work that requires heightened attention. One of the factors that may affect your ability in these respects is the use of drugs because of their effects and/or side effects. Descriptions of these effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor or pharmacist if you are unsure.

Carboplatin can cause nausea, vomiting, visual disturbances and hearing problems. If you experience this, it may affect your ability to drive or operate machinery.

If you experience any side effect that affects your ability to drive or operate machinery, avoid these activities until the event has resolved.

**3. How Carboplatin Cipla is given**

The medicinal product will always be given to you by a nurse or a doctor experienced in this kind of treatment. It is usually given in a drip by slow injection into a vein and will usually take between 15 and 60 minutes to be given. If you require any further information, ask your doctor or nurse.

Your doctor will calculate the dose for you based on your height and weight, the ability of the bone marrow to produce new blood cells and your kidney function. Your doctor will perform blood tests each week after giving you Carboplatin Cipla in order to decide on the correct next dosage for you. There will usually be a gap of 4 weeks between each dose of Carboplatin Cipla.

You may feel sick while you are being treated with Carboplatin Cipla. Your doctor may give you another medicine to reduce these effects before you are treated with Carboplatin Cipla.

The medicinal product will be diluted before use.

This medicine should be used by the intravenous (IV) route only.

The recommended dose is:

**Adults**

The recommended dose is 400 mg/m<sup>2</sup> given as a single intravenous (into the vein) dose over a period of 15 to 60 minutes.

**The elderly**

For elderly patients (over 65 years old), the dosage may need adjusting depending on your physical condition.

**Children**

There is insufficient information available to recommend a dosage for children.

**If you have received treatment previously or have kidney problems**

The dose will be adjusted, 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 tests as well as monitoring your kidney function.

**Combination therapy**

The dosage will be adjusted when carboplatin is to be given in combination with other medicines.

**Patients with risk factors**

The dosage will be reduced for patients with risk factors such as prior chemotherapy and/or radiotherapy, or low performance status.

If you have any further question on the use of this product ask your doctor or nurse.

**4. Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- Abnormal bruising, bleeding (haemorrhage), or signs of infection such as a sore throat and high temperature.
- Severe allergic reactions (anaphylaxis/anaphylactoid reactions). Symptoms of a severe allergic reaction include sudden wheeziness or tightness of chest, swelling of the eyelids, face or lips, facial flushing, hypotension, tachycardia, urticaria, dyspnoea, dizziness and anaphylactic shock.

**Very common side effects (may affect more than 1 in 10 people)**

- Reduction in blood platelets, which increases risk of bleeding or bruising,
- condition in which the number of white bloods cells called neutrophils is abnormally low,
- Low white blood cell count,
- Anaemia (a condition in which there is a decreased number of red blood cells which lead to tiredness),
- Liver function test abnormal,
- Nausea, vomiting and abdominal pain,
- Creatinine renal clearance decrease (sign of impaired kidney function),
- Blood urea increased,
- Blood alkaline phosphate increased,
- Aspartate aminotransferase increase,
- Decrease in the level of sodium, potassium, calcium and magnesium in your blood.

**Common side effects (may affect up to 1 in 10 people)**

- A disorder of the nerves which can cause weakness, tingling or numbness,
- Tingling or numbness in the hands or feet,
- Taste changes which may affect the way foods normally taste,
- Visual disturbance, rare cases of loss of vision,
- Hearing impairment,
- Respiratory and lung disorders, including difficulty in breathing or wheezing,
- Diarrhea, constipation, sore lips or mouth ulcers (mucous membrane disorders),
- Hair loss,
- Pain or discomfort in your bones, joints, muscles, or surrounding structures (musculoskeletal disorder),
- Extreme tiredness/weakness (asthenia),
- Problems with your kidneys or urine,
- Heart disorders,
- Decrease of deep tendon reflexes (stretch reflexes),
- Sensory disturbance,
- Skin disorder,
- Blood bilirubin increased (could cause yellowing of the skin),
- Blood creatinine increased (sign of impaired kidney function),
- Blood uric acid increased which may lead to gout.

**Not known (frequency cannot be estimated from available data)**

- Malaise (feeling unwell),
- Cancers caused by treatment with carboplatin (secondary malignancies),
- Feeling unwell with a high temperature due to low levels of white blood cells (febrile neutropenia),
- Bone marrow failure,
- A disorder where the red blood cells dissolve, which cause anemia, reduction in blood platelets and kidney failure (hemolytic-uremic syndrome, HUS),
- Dehydration,
- Loss of appetite,
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma,
- Disease affecting the blood vessels of the brain, such as stroke,
- Heart failure can cause shortness of breath or ankle swelling,
- Obstruction in blood vessel (embolism),
- Low/high blood pressure,
- Sores in the mouth and esophagus, which may be painful and cause difficulty swallowing,

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- Hives, rash, redness of the skin, itching,
- Redness, swelling and pain or dead skin around the injection site (injection site reaction)

#### Reporting of side effects

If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below:

#### Ireland:

HPRM Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafty@hpra.ie

**Malta:** ADR Reporting: at: www.medicinesauthority.gov.mt/adportal

### 5. How to store Carboplatin Cipla

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

After dilution: 24 hours at room temperature (25°C) or 24 hours under refrigeration (2-8°C).

Do not use this medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

The product should be diluted and used immediately after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help protect the environment.

### 6. Contents of the Pack and Other Information

#### What Carboplatin Cipla contains

The vials contain:

- The active substance carboplatin.
- Each ml of concentrate for solution for infusion contains 10mg of carboplatin.
- Each 5ml vial contains 50mg of carboplatin, each 15ml vial contains 150mg of carboplatin, each 45ml vial contains 450mg of carboplatin and each 60ml vial contains 600mg of carboplatin.
- The other ingredient is water for injections

#### What Carboplatin Cipla looks like and content of the pack

Carboplatin Cipla 10 mg/ml concentrate for solution for infusion is a clear, colourless solution free from visible particles.

pH: 5.00 - 7.00

Clear vials of Type I glass, packed in a carton.

Vials are closed with a fluoro-resin laminated bromobutyl rubber stopper with an aluminium crimp cap with a polypropylene flip-off lid.

Packs of 1 vial containing 50 mg/5ml of carboplatin.

(Red flip-off lid)

Packs of 1 vial containing 150 mg/15ml of carboplatin.

(Dark Green flip-off lid)

Packs of 1 vial containing 450 mg/45ml of carboplatin.

(Blue flip-off lid)

Packs of 1 vial containing 600 mg/60ml of carboplatin.

(Red flip-off lid)

Not all pack sizes may be marketed.

#### Marketing Authorization Holder:

**Cipla Europe NV,**

Uitbreidingstraat 80,

2600 Antwerp,

Belgium.

#### Manufacturer:

**Cipla Europe NV,**

Uitbreidingstraat 80,

2600 Antwerp,

Belgium

#### Cipla (EU) Limited

20 Balderton Street, London,

W1K6TL, United Kingdom

**S&D Pharma CZ, spol. s. r.o.,**

Theodor 28, 273 08 Pchery (Pharmos a. s. facility),

Ceská Republika 273 08

**This medicinal product is authorised in the member states of the EEA under the following names:**

Sweden	Carboplatin Cipla
Ireland	Carboplatin Cipla 10 mg/ml Concentrate for Solution for Infusion
Malta	Carboplatin Cipla 10 mg/ml Concentrate for Solution for Infusion
Germany	Carboplatin Cipla 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Italy	Carboplatino Cipla
Austria	Carboplatin Cipla 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Carboplatin Cipla 10 mg/ml concentraat voor oplossing voor infusie Carboplatin Cipla 10 mg/ml Solution à diluer pour perfusion Carboplatin Cipla 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Romania	Carboplatin Cipla 10 mg/ml Concentrat pentru soluție perfuzabilă

**This leaflet was last revised in {11/2015}**

#### The following information is intended for healthcare professionals:

Operating Instructions - Cytotoxic, carboplatin should only be administered intravenously.

The recommended dose of carboplatin for previously untreated adult patients with normal renal function, i. e. with creatinine clearance > 60 ml / min is 400 mg / m<sup>2</sup> as a single intravenous dose administered over 15-60 minutes infusion. Alternatively, the Calvert formula used to determine the dose:

Dose (mg) = target AUC (mg/ml x min) x [GFR ml/min + 25]		
Target AUC	Planned chemotherapy	Patient treatment status
5-7mg/ml .min	single agent carboplatin	Previously untreated
4-6 mg/ml .min	single agent carboplatin	Previously treated
4-6mg/ml .min	Carboplatin plus cyclophosphamide	Previously untreated

Note: With the Calvert formula, the total dose of carboplatin is calculated in mg, not mg/m<sup>2</sup>. Calvert's formula should not be used in patients who have received extensive pretreatment\*\*.

\*\*Patients are considered heavily pretreated if they have received any of the following:

- Mitomycin C
- Nitrosourea
- Combination therapy with doxorubicin/ cyclophosphamide/cisplatin,
- Combination therapy with 5 or more agents,
- Radiotherapy ≥ 4500 rad, focused on a 20 x 20 cm field or on more than one field of therapy.

Therapy with carboplatin should be discontinued in the case of an unresponsive tumour, progressive disease and/or occurrence of not tolerable side effects.

Therapy should not be repeated until four weeks after the previous carboplatin course and/or until the neutrophil count is at least 2,000 cells/mm<sup>3</sup> and the platelet count is at least 100,000 cells/mm<sup>3</sup>.

Reduction of the initial dosage by 20-25% is recommended for those patients who present with risk factors such as prior myelosuppressive treatment and low performance status (ECOG-Zubrod 2-4 or Karnofsky below 80).

Determination of the haematological nadir by weekly blood counts during the initial courses of treatment with carboplatin is recommended for dosage adjustment for subsequent courses of the therapy.

Needles or intravenous sets containing aluminum parts that may come in contact with carboplatin injection should not be used for preparation or administration. Aluminum reacts with carboplatin injection causing precipitate formation and/or loss of potency.

The safety measures for dangerous substances are to be complied with preparation and administration.

Preparation must be carried out by personnel who have been trained in the safe use while wearing protective gloves, face mask and protective clothes.

#### Renal Impairment

Patients with creatinine clearance values of less than 60 ml/min are at greater risk to develop myelosuppression.

The frequency of severe leukopenia, neutropenia, or thrombocytopenia has been maintained at about 25% with the following dosage recommendations:

Baseline Creatinine Clearance	Initial Dose (Day 1)
41-59 mL/min	250 mg/m <sup>2</sup> I.V.
16-40 mL/min	200 mg/m <sup>2</sup> I.V.

Insufficient data exist on the use of carboplatin injection in patients with creatinine clearance of

15 mL/min or less to permit a recommendation for treatment.

All of the above dosing recommendations apply to the initial course of treatment. Subsequent dosages should be adjusted according to the patient's tolerance and to the acceptable level of myelosuppression.

#### Combination Therapy:

The optimal use of carboplatin in combination with other myelosuppressive agents requires dosage adjustments according to the regimen and schedule to be adopted.

#### Paediatric population:

There is insufficient information available to recommend a dosage in the paediatric population

#### Elderly patients:

In patients of more than 65 years of age, adjustment of the carboplatin dose to the general condition is necessary during the first and the subsequent therapeutic courses.

#### Incompatibilities

This medicinal product must not be mixed with other medicinal product except those mentioned in see Special precautions for disposal and other handling.

Carboplatin may interact with aluminium to form a black precipitate. Needles, syringes, catheters or IV administration sets containing aluminium parts that may come into contact with carboplatin should not be used for preparation or administration of carboplatin. Precipitation can lead to a reduction of the antineoplastic activity.

#### Shelf life and storage

##### After dilution

Chemical and physical in-use stability has been demonstrated after dilution with infusion fluids described in section 6.6 for 24 hours at room temperature (25°C) or 24 hours under refrigeration (2-8°C).

From a microbiological point of view, the product should be used immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C).

Store the vials in the outer carton in order to protect from light.

#### Special precautions for disposal and other handling

This product is for single dose use only.

Solutions should only be used if clear and particle free.

#### Disposal:

Any unused product or waste material should be disposed of in accordance with local requirements.

#### Dilution:

The product must be diluted before use. It may be diluted with 5% Glucose Injection, or 0.9% Sodium Chloride Injection, to concentrations from 2.0 mg/ml and as low as 0.4 mg/ml (400 micrograms/ml).

#### Guidelines for the safe handling of anti-neoplastic agents:

1. Carboplatin should be prepared for administration only by professionals who have been trained in the safe use of chemotherapeutic agents
2. This should be performed in a designated area.
3. Adequate protective gloves should be worn.
4. Precautions should be taken to avoid the drug accidentally coming into contact with the eyes. In the event of contact with the eyes, wash with water and/or saline.
5. The cytotoxic preparation should not be handled by pregnant staff.
6. Adequate care and precautions should be taken in the disposal of items (syringes, needles, etc.) used to reconstitute cytotoxic drugs. Excess material and body waste may be disposed of by placing in double sealed polythene bags
7. and incinerating at a temperature of 1,000 °C. Liquid waste may be flushed with copious amounts of water.
8. The work surface should be covered with disposable plastic-backed absorbent paper.
9. Use Luer-Lock fittings on all syringes and sets. Large bore needles are recommended to Minimise pressure and the possible formation of aerosols. The latter may also be reduced by the use of a venting needle.

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Body text : 9pt Sub Heading : 10pt Main Heading : 12pt Leading between two line: 3pt

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**PACKAGING DEVELOPMENT**

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**NOTE TO THE PRINTER :**

- Return approved artwork alongwith the proof.
- The proof must be verified against the approved hardcopy, should be certified and signed by an authorised QA person. The unsigned proof will not be accepted.
- Colour scheme must be as approved by packaging development co-ordinator.
- Any deviation must be brought to the notice of packaging development co-ordinator immediately.
- For any clarification, please contact packaging development co-ordinator immediately.