**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**CARBOPLATIN–TEVA 10 mg/ml CONCENTRATE FOR SOLUTION FOR INFUSION**

carboplatin

**Read all of this leaflet carefully before you start using this medicine.**
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or pharmacist or nurse.
• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
• If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**WHAT IS IN THIS LEAFLET**



## 1. What Carboplatin-Teva is and what it is used for

Carboplatin-Teva is a platinum containing compound. It is an anti-cancer agent, which is used either alone or in combination with other medicines.

Carboplatin-Teva is used to treat advanced ovarian cancer and lung cancer (small cell cancer of the lung).

Ask your doctor or nursing staff if you need additional information.

## 2. What you need to know before you receive Carboplatin-Teva

**DO NOT receive Carboplatin-Teva if you:**
- are allergic (hypersensitive) to carboplatin, cisplatin or other platinum-containing compounds or any of the other ingredients of this medicine (listed in section 6)
- have severe kidney problems
- have any bone marrow problems
- suffer from significant bleeding (bleeding tumors)
- are pregnant, may be pregnant or breast-feeding
- are due to receive, or have recently received, the yellow fever vaccine.

**Warnings and precautions**
**Talk to your doctor before you receive this medicine if you:**
- are elderly (over 65 years old).

**Other precautions whilst you are receiving Carboplatin-Teva:**
- Your nervous system function will be checked regularly.
- Your doctor may give you blood or urine tests to check your blood composition, kidney or liver function before, during and after treatment with Carboplatin. This is necessary to continue therapy.
- Your doctor may prescribe anti sickness medicines to prevent nausea and vomiting.

- If you have headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss, tell your doctor.
- If you develop extreme tiredness with decreased number of red blood cells, and shortness of breath (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), tell your doctor.
- If you have fever (temperature greater than or equal to 38°C), or chills, which could be signs of infection, tell your doctor immediately. You may be at risk of getting an infection of the blood.
- During treatment with carboplatin 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**
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-Teva**
Tell your doctor if you are taking, have recently taken or might take any other medicines. In particular, **talk to your doctor if you are taking any of the following medicines:**

- Myelosuppressive medicines such as cyclophosphamide or fluorouracil
- Any drugs which can cause damage to either your kidneys or inner ears e.g.
  - **Aminoglycoside antibacterials**, such as gentamicin, streptomycin
  - **Diuretics** such as bumetanide or furosemide
  Carboplatin may increase the toxic effects of these drugs. The combination of carboplatin with these drugs should be avoided
- **Cisplatin** (another anti-cancer agent)
- **Vaccines** (live or killed virus)
- **Oral anticoagulants** (medicines to thin the blood)
- **Cyclosporin, tacrolimus or sirolimus** (used to suppress the immune system)
- **Phenytoin** or **fosphenytoin** (medicines for epilepsy)
- **Chelating agents** (substances/chemicals used to bind or inactivate metal poisons in the body).

**DO NOT** use Carboplatin-Teva if you are due to receive, or have recently received, yellow fever vaccine.

**Pregnancy, breast-feeding and fertility**
Pregnancy
• Carboplatin-Teva should not be given to you if you are pregnant unless clearly indicated by your doctor, due to the possible risk of abnormalities in the developing foetus.
• If you become pregnant or suspect that you may be pregnant during therapy, **you must tell your doctor immediately**. If you are pregnant or become pregnant during therapy, genetic counselling should be provided.
• **Female patients** should use an effective method of contraception, e.g. the barrier method or condoms, to avoid getting pregnant during treatment, and for at least 6 months after treatment with carboplatin.
• **Male patients** receiving treatment with carboplatin should also take adequate contraception precautions while on treatment and for at least 3 months after treatment with carboplatin to ensure that their partner does not become pregnant for the same period.

Breast-feeding
• You **should not** breast-feed during your treatment with Carboplatin-Teva.

Fertility
Carboplatin-Teva may lead to irreversible infertility. Patients who may wish to become pregnant or father a child in future are advised to seek specialist fertility advice prior to treatment.

**Driving and using machines**
Carboplatin-Teva can cause nausea, vomiting and vision abnormalities, and may affect your ability to drive or operate machines. DO NOT drive or operate machinery until you are sure you are not affected.

**Carboplatin-Teva contains Mannitol.**
If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

## 3. How to receive Carboplatin-Teva

• The correct amount of medicine to treat your particular condition has been decided by your doctor. This will be given by injection into a vein (intravenous injection) or it will be diluted in intravenous fluid and given slowly by an IV drip.
• Needles or intravenous sets containing aluminium parts that may come in contact with carboplatin should not be used for preparation or administration. Aluminium reacts with carboplatin causing precipitate formation and/or loss of potency.
• Carboplatin-Teva should only be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents.
• Adequate diagnostic and treatment facilities must be readily available to ensure appropriate management of therapy, and treatment of possible complications.

The usual dose is:
**• Adults**
400 mg/m$^2$ 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.

**• If you have received treatment previously or have kidney problems**
Your dosage will be adjusted to suit you.

**• Combination therapy**
The dosage will be adjusted when Carboplatin-Teva 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 receive more Carboplatin-Teva than you should**
There is no specific antidote for Carboplatin-Teva over dosage. If you received too much carboplatin, the doctor will stop the therapy and treat the symptoms.

**If administration of Carboplatin-Teva is forgotten**
Your doctor will decide on what time you will receive this medicine. If you think you have missed a dose, please contact your doctor as soon as possible.

## 4. Possible side effects

Like all medicines, Carboplatin-Teva can cause side effects, although not everybody gets them.

**Allergic reactions**

If you get any of the following serious side effects, tell your doctor immediately:

- signs and symptoms that may indicate a serious allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives; low blood pressure). This is a very serious but rare side effect. You may need urgent medical attention.
- chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome

The following side effects have also been reported:

Very common (affects more than 1 patient in 10):

- nausea and vomiting
- stomach pain
- reduction in the number of platelets associated with bruises and abnormal bleeding (thrombocytopenia)
- reduction in the number of red blood cells (anaemia: this may cause tiredness)
- reduction in the number of white blood cells, which may lead to frequent infections
- changes in blood and urine test results.

Common (affects fewer than 1 in 10 and more than 1 in 100):

- sensation of tingling, pricking, or numbness of the skin with no apparent physical cause (paraesthesia), slow reflexes, nervous system symptoms
- ringing in ears (tinnitus), hearing loss, hearing problems
- transient eye problems such as transient loss of sight
- taste alteration
- hair loss (alopecia)
- infections
- haemorrhage
- allergic reactions such as rash, fever or low blood pressure
- numbness or weakness in the arms or legs
- heart disorders
- respiratory disorders, lung disease, wheezing or coughing
- diarrhoea and constipation
- skin or mucous membrane disorders
- urogenital disorder
- tiredness and weakness
- changes in blood test results.

Rare (affects fewer than 1 in 1,000 and more than 1 in 10,000):

- loss of vision.

Frequency not known (frequency cannot be estimated from the available data):

- reduced function of the bone marrow (myelosuppression)
- secondary cancer
- fever and chills
- haemolytic-uraemic syndrome
- dehydration
- anorexia

- low blood sodium levels
- stroke
- heart failure
- blocked blood vessels, high or low blood pressure
- mouth ulcers
- rash, itching or reddening of the skin
- skin reactions at the injection site
- general feeling of being unwell
- lung infection
- pancreatitis
- a group of symptoms such as headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss (symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder)
- muscle cramping, muscle weakness, confusion, visual loss or disturbances, irregular heartbeat, kidney failure or abnormal blood test results (symptoms of tumor lysis syndrome which can be caused by the rapid breakdown of tumour cells) (see section 2).

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Carboplatin-Teva

**Keep out of the reach and sight of children.**
Do not store above 25ºC. Keep the vial in the outer carton.
After dilution in Water for Injections, 0.9% sodium chloride injection or 5% dextrose injection, 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 not be longer than 24 hours at 2ºC to 8ºC.
Since the formulations of carboplatin do not contain preservatives, it is recommended that any solution remaining after this time should be discarded.
Do not use Carboplatin-Teva after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.
Only use this product if it is a clear, colourless to faintly yellow solution, free from fibres and particles of foreign matter.
For single use only.
Once opened any unused solution should be discarded using the appropriate precautions. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What Carboplatin-Teva contains**
• The active substance is carboplatin 10 mg/ml.
• The other ingredients are mannitol and water for injections.

**What Carboplatin-Teva looks like and contents of the pack**
• Carboplatin-Teva Concentrate for Infusion comes as a clear, colourless to faintly yellow solution, free from particles.
The product is available in packs containing a single 5 ml, 15 ml, 45 ml, or 60 ml clear amber glass vial.
• Each 5 ml vial contains 50 mg of the active ingredient carboplatin

• Each 15 ml vial contains 150 mg of the active ingredient carboplatin
• Each 45 ml vial contains 450 mg of the active ingredient carboplatin
• Each 60 ml vial contains 600 mg of the active ingredient carboplatin.

**Marketing Authorisation Holder and Manufacturer**
The Marketing authorisation holder is:
Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
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The manufacturer is:
Pharmachemie B.V.,
Swensweg 5,
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2003 RN Haarlem
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**This leaflet was last revised**: **March 2024**