

Carboplatine Mylan

solution for infusion

10 mg/ml

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, 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 Carboplatine Mylan 10 mg/ml, solution for infusion is and what it is used for
2. What you need to know before you use Carboplatine Mylan 10 mg/ml, solution for infusion
3. How to use Carboplatine Mylan 10 mg/ml, solution for infusion

1. What Carboplatine Mylan 10 mg/ml, solution for infusion is and what it is used for

Pharmacotherapeutic group – ATC code: L01XA02 OTHER ANTINEOPLASTIC AGENTS (L: Antineoplastic and immunomodulating agents)
This medicinal product is a cytostatic agent which prevents cell growth. It is recommended in certain diseases of the ovary, bronchi, and upper aero-digestive passageways.

2. What do you need to know before you use Carboplatine Mylan 10 mg/ml, solution for infusion

Do not use Carboplatine Mylan 10 mg/ml, solution for infusion in the following cases:

- if you are allergic (hypersensitive) to the carboplatin, other products containing platinum or any of the other ingredients of this medicine (listed in section 6);
- if you have pre-existing severe renal impairment (creatinine clearance < 30 ml/min),
- if you have reduced bone marrow function (severe myelosuppression),
- if you have a bleeding tumor,
- In combination with the yellow fever vaccine.

IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Take special care with CARBOPLATINE MYLAN 10 mg/mL, solution for infusion:

Carboplatin must be administered by slow intravenous infusion. Only the doctor is qualified to assess the clinical indications for Carboplatin, its dosage, route of administration, and the monitoring procedures that it requires.

Talk to your doctor or pharmacist before using Carboplatine Mylan 10 mg/mL, solution for infusion:

- if your blood cell count is less than normal (your doctor will check this)
- if your kidneys do not work as they should, carboplatin effects on blood cells (hematopoietic system) are more important and prolonged than if you have normal renal function.
- If you are elderly (over 65 years old) because you will be more likely to develop side effects of carboplatin on blood cells and nervous system
- If you have hearing problems
- If you plan to receive vaccination or have just received one, included live vaccines or live-attenuated vaccines.

During treatment

Blood tests should be done to evaluate if your hepatic and renal function are correct and if the treatment does affect your 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.

If you have headache, altered mental functioning, seizures and abnormal vision (from blurriness to vision loss), contact 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 in the blood, abnormal bruising (thrombocytopenia) and kidney disease where you pass little or no urine (symptoms of Haemolyticuraemic 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.

If your hearing is reduced or worsens during or after treatment or if you notice visual disturbances including loss of vision, tell your doctor.

Children and adolescents

The use of carboplatin is not recommended in children and adolescents due to insufficient information available on the dose to administer.

Other medicines and Carboplatine Mylan 10 mg/ml, solution for injection

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

If you take one of the following medicines, tell your doctor because they might interact with Carboplatin Mylan.

- The use of anticoagulation treatment
- Other anti-cancer drugs
- Yellow fever vaccine
- Live-attenuated vaccines
- Phenytoin, fosphenytoin (used to treat various types of convulsions and seizures)

4. Possible side effects

5. How to store Carboplatine Mylan 10 mg/ml, solution for infusion

6. Content of the pack and other information

- Cyclosporin, tacrolimus and sirolimus
- Aminoglycosides, Vancomycin, Capreomycin (known to be toxic for kidney and ear (hearing and balance))
- Loop Diuretic (known to be toxic for kidney and ear (hearing and balance))

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 or pharmacist for advice before taking this medicine.

Pregnancy

You should not be given Carboplatin Mylan if you are pregnant, unless strictly indicated by your doctor. If you are treated by carboplatin during your pregnancy or if you plan to have a baby during treatment, you should tell immediately your doctor and discuss about risks for child.

Breastfeeding

It is not known whether carboplatin is excreted in breast milk. You should not breast-feed during the treatment by Carboplatin Mylan.

Fertility

Women of childbearing potential must use effective method of contraception before and during treatment with carboplatin.

It is recommended to men treated by carboplatin to not father a child during treatment and up to 6 months afterwards and to ask advice about spermatic preservation prior to initiation of the therapy because of the possibility of irreversible infertility due to therapy with carboplatin.

Driving and using machines

Carboplatin may cause side effects (nausea, vomiting, vision abnormalities, hearing and balance problems), it is recommended to not drive or use machines if you experience these symptoms.

3. How to use Carboplatine Mylan 10 mg/ml, solution for infusion

This medicine will always be administered by a nurse or a doctor.

It is usually administered into a blood vein by slow intravenous infusion as a drip over a period of 15 to 60 minutes.

The recommended dose of carboplatin depends on:

- Your height and weight
- Function of blood cells production (hematopoietic system)
- Renal function
- If you have previously been given carboplatin or if you are getting other anti-cancer treatment

Your doctor will choose the appropriate dose in your case. This medicine will be diluted before administration.

The usual dose of carboplatin is 400 mg per square meter of body surface area (calculated from your height and weight).

The dose of carboplatin may be adjusted if you

- suffer from kidney problems,
- suffer from bone marrow dysfunction,
- are elderly (over 65 years old),
- are given carboplatin in combination with another treatment.

Your general condition and response to the treatment will be closely observed before, during and after the carboplatin treatment.

If you received more Carboplatine Mylan 10 mg/ml, solution for infusion than you should:

This medicine is exclusively administered by medical personnel, risk of overdose is unlikely.

Contact immediately your doctor if you think that you may have received too high dosage of Carboplatin Mylan.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicinal products, Carboplatine Mylan 10 mg/mL, solution for infusion can cause side effects, although not everybody gets them. Contact your doctor or go to the nearest hospital immediately, if you experience one of the following effect:

Very common (occur in more than 1 in 10 patients):

- Reduction in blood cells count in case of bone marrow depression (myelosuppression), including white blood cells (which may cause increased infection and/or fever), red blood cells (which may cause paleness, tiredness or shortness of breath) and low platelet count (which may increase bleeding or abnormal bruising (bleeding complications)). Your doctor may decide to place you under medical supervision.
- Anemia (in case you had decreased number of red blood cells which

leads to tiredness).

Common (occur in up to 1 in 10 patients)

- Allergic reactions with severe rash including itching, swelling of the face, lips, tongue or any other body part, shortness of breath, difficulty in breathing, wheezing and you may feel weak.
- Visual disturbance including rare cases of loss of vision.
- Ringing in the ears (tinnitus), hearing problems and loss of hearing.
- Respiratory disorders.

Not known (cannot be estimated from available data):

- Haemolytic uraemic syndrome (disease characterized by an acute kidney failure, a decreased red blood cells count (macroangiopathic hemolytic anemia) and a low blood platelet count).
- Bleeding in the brain which may lead to cerebral stroke or unconsciousness.
- Cardiac failure.
- Redness, swelling and pain or dead skin where the injection is given (injection site reactions).
- Abnormal liver enzyme levels. Your doctor may decide to place you under medical supervision.
- Liver problems.
- Kidney problems.
- A group of symptoms such as headache, altered mental functioning, seizures and abnormal vision (from blurriness to vision loss) (Reversible Posterior Leukoencephalopathy Syndrome, a rare neurological disorder).
- Pancreatitis.
- Lung infection.
- 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).

The use of carboplatin may be linked to tumour development (secondary growths) in the body.

Other side effects are:

Very common (occur in more than 1 in 10 patients):

- Nausea and vomiting.
- Cramps and abdominal pains.
- Kidney damage (renal toxicity).
- Increased urea in blood. Your doctor may decide to place you under medical supervision.
- Decreased salts rate in blood (sodium, potassium, calcium and magnesium)

Your doctor may decide to place you under medical supervision.

Common (occur in up to 1 in 10 patients):

- Other allergic reactions.
- Tingling, pins and needles (peripheral neuropathies).
- Joint and muscular pains.
- Central nervous system damage such as decreased reflexes.
- Altered taste.
- Cardiovascular disorders.
- Diarrhea, constipation, mucous membrane disorders (nose).
- Hair loss.
- Skin disorders.
- Unusual weakness or tiredness.
- Increased level of bilirubin.
- Increased level of creatinin and uric acid in your blood.

Not known (cannot be estimated from available data):

- Dehydration.
- Loss of appetite (anorexia).
- Decreased level of sodium in the blood.
- Obstruction in blood vessel in your heart, high blood pressure, low blood pressure.
- Sore lips or mouth ulcers (stomatitis).
- Allergic reactions: rash, hives, skin redness and itching.
- Malaise.

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 the national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carboplatine Mylan 10 mg/ml, solution for infusion

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton after {EXP}. The expiry date refers to the last day of that month. Store below 25°C. Store in the original package in order to protect from light.

After dilution of product, immediate use is recommended. However, stability of the solution has been demonstrated for 3 hours at



For the attention of the health care team:

It is recommended to use pipe with filtering membrane with micropores up to $\leq 0,2 \mu\text{m}$ or $\leq 5 \mu\text{m}$ diameter.

Filtration does not change solution's composition.

As with any cytotoxic agent, the preparation and handling of this product require that all precautions should be taken to ensure the protection of the manipulator and his/her environment, under the necessary conditions of safety for the patient.

The following precautions must be adopted in addition to those usually observed in maintaining the sterility of injections:

- Wear a long-sleeved gown with close-fitting cuffs, so as to avoid any splashes of solution on the skin,
- Also wear a disposable surgical mask and wrap-around goggles,
- Wear disposable PVC (not latex) gloves, after scrubbing,
- Prepare the solution on a drape,
- Discontinue the infusion should the injection go outside the vein,

temperatures below 25°C after dilution in a solution of:

- 5 % dextrose,
- 0.9 % sodium chloride.

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. Further information

What Carboplatine Mylan 10 mg/ml, solution for infusion contains

• The active substance is:

Carboplatin: 10 mg For 1 mL.

• The other component is: water for injection.

What Carboplatine Mylan 10 mg/ml, solution for infusion looks like and contents of the pack

This medicine is a solution for infusion

This medicinal product is supplied in vial of 5 ml, 15 ml, 45 ml; box of 1.

Benta S.A.L., Dbayeh - Lebanon



Under license from

Mylan S.A.S.

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This leaflet was last approved on December 2019.

Detailed information on this medicine is available on the website of the ANSM (France).

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

- Discard any materials used in preparing the solution (syringes, compresses, drapes, vial) using a container reserved for this purpose,
 - Destroy the toxic waste,
 - Handle excreta and vomitus with care.
- Pregnant women must avoid handling cytotoxic agents.