

# Cisplatine

## MYLAN 1 mg/mL

10 mg 10 mL

1 vial of 10 mL  
concentrate for  
solution for infusion

IV intravenous  
infusion

Mylan

Please read all of this leaflet carefully before using this medicinal product.

Keep this leaflet. You may need to read it again.

• If you have any further questions, ask your doctor or pharmacist.

• 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, or pharmacist. This includes any possible side effects not listed in this leaflet.

The active substance is: cisplatin (1 mg/ml).

The other ingredients are: sodium chloride, hydrochloric acid, water for injections.

Benta S.A.L.,  
Dbayeh - Lebanon

**BPI**

Under license from

Mylan S.A.S.

117 Allée des Parcs  
69800 SAINT-PRIEST - FRANCE

### 1. What is Cisplatine Mylan, concentrate for solution for infusion and when should this medicinal product be used?

This medicinal product is presented as a concentrate for solution for infusion in vial.

Box of 1 vial of 10ml.

Pharmacotherapeutic group: ALKYLATING AND RELATED AGENTS  
(L: Anticancer and Immunosuppressant drugs) Code ATC: L01XA01

This medicinal product is indicated in treatment of certain disease of the ENT sphere, genitourinary sphere, oesophagus and stomach.

### 2. What you need to know before you use Cisplatine Mylan 10 mg/10 ml, concentrate for solution for infusion?

Do not take Cisplatine Mylan 10 mg/10 ml, concentrate for solution for infusion, in the following cases:

• you are allergic to cisplatin or any other medicine that contains platinum compounds or any of the other ingredients of this medicine;

• you have kidney problems (renal dysfunction);

• you are pregnant or breast-feeding;

• combined with yellow fever vaccine;

• you suffer from dehydration;

• your hearing is impaired;

• you suffer from severe suppression of bone marrow functionality, symptoms may be: extreme tiredness, easy bruising or bleeding, occurrence of infections.

Take special precautions with Cisplatine Mylan, concentrate for solution for infusion.

#### Special warnings

Talk to your doctor or pharmacist before using Cisplatine Mylan 10 mg/10 ml, concentrate for solution for infusion.

In order to reduce the risk of renal insufficiency, which may be permanent, it is essential to maintain diuresis at least equal to 3 liters per 24 hours.

Monitoring of diuresis and institution of preventative hyperhydration must be applied and continued for several days, if required, particularly if nausea and vomiting are present.

Unless otherwise advised by your doctor, it is not recommended to take Cisplatine Mylan 10 mg/10 ml if you suffer from a cardiorespiratory pathology in particular, contraindicating hyperhydration.

#### Precautions for use

Treatment requires clinical and biological monitoring before each administration of the medicinal product (kidney and liver function tests, counts of different blood cells, monitoring of electrolytes, particularly blood level of magnesium, calcium, potassium and sodium).

Furthermore, an audiogram and a neurological examination must be carried out prior treatment and at regular intervals.

As with medicinal products of the same therapeutic group, cisplatin may induce transient or permanent sterility in men. The preservation of sperm is to be considered in the event of the desire for subsequent fatherhood.

#### During the treatment:

If spillage of cisplatin occurs, the contaminated skin must immediately be washed with soap and water. If cisplatin is injected outside the blood vessels, administration should be stopped immediately. Cisplatin on the skin can result in tissue damage (cellulitis, fibrosis and necrosis).

#### Other medicines and Cisplatine Mylan 10 mg/10 ml, concentrate for solution for infusion

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

Please note that these statements may also apply to medicines used some time ago or at some time in the future.

• Use of medicines that inhibit the bone marrow function or radiation can increase the adverse effects of cisplatin on the bone marrow.

• The toxicity of bleomycin and methotrexate (other medicines for cancer treatment) may increase when administered with/or after cisplatin because of potentially reduced renal elimination caused by cisplatin nephrotoxicity.

• Cisplatin toxicity may severely affect the kidneys when administered with agents that may cause side effects in the kidneys, such as those for the prevention/treatment of certain infections (antibiotics: cephalosporins, aminoglycosides, and/or antifungals: amphotericin B) and contrast agents (used in medical imaging).

• Cisplatin toxicity may also affect hearing when administered with aminoglycosides.

• Administration of drugs that elevate your rate of bodily urine excretion (loop diuretics) combined with cisplatin (where the cisplatin dose is not more than 60mg/m<sup>2</sup> and urine secretion is not less than 1000 ml per 24 hours) may result in toxic effects on kidneys and hearing.

• The first signs of hearing damage (dizziness and/or tinnitus) may remain hidden when – during your treatment with cisplatin – you are also being administered agents to treat hypersensitivity, feeling or being sick, mental problems (antihistamines, such as buclizine, cyclizine, loxapine, mectizone, phenothiazines, thioxanthenes and/or trimethobenzamides).

• Cisplatin given in combination with ifosfamide may result in hearing impairment.

• Administration of pyridoxine and atretamine may reduce the effect of cisplatin therapy.

• Administration of cisplatin prior to treatment with paclitaxel may result in severe nerve damage.

• The combined use of cisplatin with bleomycin and etoposide may decrease lithium levels in the blood. Therefore, lithium levels should be checked on a regular basis.

• Cisplatin reduces the amount of certain medicines used to treat epilepsy (such as phenytoin) in your blood thereby reducing the effect on the treatment of epilepsy. You should not start a new treatment for epilepsy while you are on cisplatin therapy.

• Cisplatin may have an adverse impact on the effectiveness of agents preventing coagulation (anticoagulants). Therefore, coagulation should be checked more often during combined use.

• Cisplatin in combination with drugs that inhibit the immune system (including ciclosporin and tacrolimus) can cause excessive suppression of the immune system with the risk of increased production of white blood cells (lymphocytes).

• You should not receive any vaccinations containing live viruses (including yellow fever vaccinations) when undergoing treatment or within six months after the end of treatment with cisplatin.

#### Pregnancy, breast-feeding and fertility

This medicine is contraindicated during pregnancy, breast-feeding and has potential effects on fertility (male or female) that should be evaluated with the doctor prior to initiation of treatment.

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.

#### Driving and using machines

Cisplatin may cause side effects such as feeling sleepy and/or vomiting. If you suffer from either of these conditions, then you should not operate any machines that require your full attention.

### 3. How to take Cisplatine Mylan 10 mg/10 ml, concentrate for solution for infusion?

#### Posology

The dosage varies according to the patient.

The recommended dose in adults and children is 50 to 120 mg/m<sup>2</sup> every 3 to 6 weeks as a single infusion or by divided administration over 5 days. The doses of Cisplatin may be modified in association with other drugs.



Renal, auditory, haematological and neurological functions should be monitored regularly in view of possible adjustment of the dosage of cisplatin.

**If you have the impression that the effect of Cisplatin Mylan, concentrate for solution for infusion is too strong or too weak, talk to your doctor or pharmacist about it.**

#### **Method of administration**

**Strict intravenous use, by infusion after dilution.**

**Precautions to be taken and instructions for preparation and handling of this medicinal product:**

**For the attention of the healthcare team:**

As with any cytostatic 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,
- 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.

**If you use more Cisplatin Mylan 10 mg/10 ml, concentrate for solution for infusion than you should:**

You may experience increased side effects which may include kidney failure, liver failure, deafness, changes to vision, reduced production of blood cells and conditions such as feeling sick, being sick and inflammation of nerves. Your doctor may give you symptomatic treatment for these side effects.

In case of overdose, renal and auditory function should be very closely monitored, and complete blood counts should be carried out.

Haemodialysis may be carried out so as to avoid any excessive binding of the product to the kidneys.

**Consult your doctor or pharmacist immediately.**

#### **4. What are the possible adverse reactions?**

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

**If you experience any side effect it is important that you inform your doctor before your next treatment. If any of the following side effects happen, you may need urgent medical attention. Tell your doctor immediately, if you notice any of the following:**

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, mouth or throat, shortness of breath or wheezing, increased heart rate and fall in blood pressure,
- reduction in number of all types of blood cells due to depression of bone marrow including white blood cells, red blood cells (which can make the skin pale and cause weakness or breathlessness) and platelets,
- a disease condition characterised by reduction in the number of red blood cells, platelets and kidney failure (haemolytic uraemic syndrome),
- suppression of the immune system which may cause more frequent infections,
- blood poisoning (sepsis) may occur,
- over production of a hormone causing fluid and sodium retention,
- damage to the nervous system, characterised by tickling, itching or tingling without cause,
- involvement of peripheral nerves,
- loss of certain types of brain function,
- damage to part of the brain due to bleeding or reduced blood supply (stroke),
- a rapid increase in abnormal white blood cells (acute leukaemia),
- problem with the spinal cord,
- loss of certain functions of brain which can lead to excessive fatigue, rapid or slow heart rate, blood pressure fluctuations, shortness of breath and abdominal distention,
- loss of sight (blindness),
- loss of hearing or deafness,
- heart attack,
- disease of the blood vessels of heart which may be due to thickening of the walls of these blood vessels thereby narrowing it and restricting blood flow to heart,
- severe pain or swelling in either of the legs, chest pain or difficulty breathing (possibly indicating harmful blood clots in a vein) (may affect up to 1 in 10 people)
- blockage of blood vessels in the lungs,
- kidneys problems (you may notice pain in the back, little or no urine being produced or the urine may be cloudy or have blood in it) or kidney failure,
- infection or injury at the site of infusion.

Other possible side effects may occur:

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

- reduced level of sodium in your blood, fever.

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

- change in your heartbeats (arrhythmia), including reduced heartbeat (bradycardia), accelerated heartbeat (tachycardia).

**Uncommon** (may affect up to 1 in 100 people)

- low level of magnesium in your blood, decreased sperm count and abnormal ovulation.

**Rare** (may affect up to 1 in 1,000 people)

- inflammation of mucous membranes of the mouth (stomatitis).

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

- increased blood amylase and bilirubin in blood, increase of liver enzymes, reduced level of electrolytes (calcium, phosphate, potassium) with muscle cramping and/or changes in an electrocardiogram (ECG),
- increased amount of uric acid in blood,
- dehydration,
- involuntary contraction of muscles (tetany),
- blurred vision and ringing in the ears (tinnitus),
- heart disorder,
- changes in blood flow to the fingers and toes (Raynaud's syndrome),
- loss of appetite, nausea, vomiting, diarrhea,
- hiccups,
- loss of hair,
- rash,
- muscle cramps,
- weakness (asthenia),
- generally feeling unwell.

#### **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 directly via the national reporting.

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

#### **5. How to store Cisplatin Mylan 10 mg/10 ml, concentrate for solution for infusion?**

Do not store above 25°C, protected from light.

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 box.

Do not refrigerate or freeze, as an undissolvable precipitate could be formed.

Only a clear solution must be administered to the patient.

After dilution, the product must be used immediately.

Do not use Cisplatin Mylan 10 mg/10 ml, concentrate for solution for infusion if you notice visible signs of deterioration.

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 protect the environment.

**This leaflet was last revised on January 2019**

#### **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