

Epirubicine

MYLAN 2 mg/mL

epirubicin hydrochloride

10 mg / 5 mL

20 mg / 10 mL

50 mg / 25 mL

200 mg / 100 mL

1 vial
solution for infusion

IV intravenous use
only

 Mylan

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.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

The active substance is: For 1 ml

Epirubicin hydrochloride.....2 mg

A 5 ml vial contains 10 mg of epirubicin hydrochloride.

A 10 ml vial contains 20 mg of epirubicin hydrochloride.

A 25 ml vial contains 50 mg of epirubicin hydrochloride.

A 100 ml vial contains 200 mg of epirubicin hydrochloride.

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

Benta S.A.L.,
Dbayeh - Lebanon



Under license from

Mylan S.A.S.

117 Allée des Parcs

69800 SAINT-PRIEST - FRANCE

What is Epirubicine Mylan 2 mg/ml, solution for infusion and what it is used for?

This medicine is available as a solution for injection in 5 ml, 10 ml, 25 ml or 100 ml vials. It is part of the cytotoxic antibiotics and related products class (Anthracyclines and related products). Box of 1 vial.

This medicine is a cytostatic agent: it prevents the growth of certain cells. It is in particular recommended in certain breast, ovary, lung, oto-rhino-laryngology and digestive apparatus diseases.

Before you use Epirubicine Mylan 2 mg/ml, solution for infusion

Do not use Epirubicine Mylan 2 mg/ml, solution for infusion:

- if you are pregnant,
- if you are breast-feeding,
- if you suffer from heart disease with myocardial insufficiency (in the cardiac muscle),
- combined with the vaccine against the yellow fever (see the section Taking or using other medicines).

Discuss with your doctor, if you are unsure about anything.



Take special care with Epirubicine Mylan 2 mg/ml, solution for infusion

Special warnings

This treatment can only be administered under STRICT MEDICAL MONITORING.

This usually includes:

- medical examination.
- biological tests indicating the condition of the following: blood (total blood count), and the hepatic function (liver),
- cardiac monitoring,
- regular haematological monitoring is required.

This medicine **should not be used** in combination with live attenuated vaccines (measles, german measles, mumps, poliomyelitis, tuberculosis, chickenpox, except the vaccine against yellow fever, see the section "This medicine must not be used in the following cases"), *phenytoin* or *fosphenytoin* (medicines used for the treatment of epilepsy) (see the section "Taking or using other medicines").

Precautions for use

The medical monitoring is particular close in case of hepatic failure, blood count anomalies and history of heart disease.

Do not forget to inform your doctor if you have received a radiotherapy treatment.

Discuss with your doctor or your pharmacist, if you are unsure about anything.

Keep out of the reach of children.

This medicine contains 3.54 mg of sodium per ml: to be taken into account in persons who follow a strict low sodium diet.



Pregnancy - Breast-feeding

This medicinal product must not be used if you are pregnant or if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

List of excipients with well-known effects: sodium.



Taking other medicines

This medicine must not be used in combination with the vaccine against yellow fever (see the section "This medicine must not be used in the following cases").

This medicine **should not be used** in combination with live attenuated vaccines (measles, german measles, mumps, poliomyelitis, tuberculosis, chickenpox, except the vaccine against yellow fever, see the section "This medicine must not be used in the following cases"), *phenytoin* or *fosphenytoin* (medicines used for the treatment of epilepsy) (see the section "Special warnings").

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to take Epirubicine Mylan 2 mg/ml, solution for infusion?

Dosage

Always take Epirubicin as your doctor has told you. Discuss with your doctor or your pharmacist, if you are unsure about anything. The dose administered must be evaluated as a function of the clinical condition of the patient (liver, heart, kidney).

Method and route of administration

Intravenous use only.

The medicine is injected slowly via the tubing of an intravenous infusion of isotonic glucose solution.

Warning!

It is extremely important to ensure that the administration is intravenous.

Any extravasation may cause a necrosis of the surrounding tissue. In case of extravasation, the administration should be stopped immediately.

To the attention of the healthcare personnel:

Like for all cytotoxic agents, the preparation and handling of this product require a set of precautions that ensure the protection of the operator and his/her environment, under the conditions required for the patient. The following is required in addition to the usual precautions to preserve the sterility of preparations for injection:

- wear a long-sleeve tight cuff laboratory coat, in order to prevent any projection of the solution on the skin,
- also wear a disposable surgical mask and safety eyeglasses,
- wear disposable gloves, after aseptically washing the hands,
- prepare the solution on a work area liner,
- stop the infusion in case of injection outside the vein,
- dispose of any material used for the preparation of the solution (syringes, compresses, liners, vial) in a container kept for this effect,
- destroy the toxic waste,
- handle excreta and vomit with care.

Pregnant women should not handle cytotoxic agents.

Frequency of administration and duration of treatment

Each treatment is administered at an interval of 3 to 4 weeks.

The duration of treatment is defined by your doctor.

Possible side effects

Like all medicines, Epirubicine Mylan 2 mg/ml, solution for infusion can cause side effects.

The following may occur during treatment:

- hair loss. It is observed in 90 % of cases, but it is reversible on stopping the treatment,
 - inflammation of the oral mucosa,
 - decrease in white blood cells and platelets (blood elements that play a major role in blood coagulation). This decrease in white blood cells could be accompanied of shivering and fever, which requires an immediate medical opinion,
 - digestive disorders: nausea, vomiting and loss of appetite. These disorders could be eliminated or avoided with an appropriate anti-nausea treatment,
 - abdominal pain, diarrhoea,
 - menstruation may be suppressed. The treatment could result in a disappearance of spermatozooids and sperm fluid,
 - heart disorders are usually prevented through regular monitoring; rarely, heart failure.
- They must be reported to the doctor who follows your treatment.

The passage of the medicine outside the vein can provoke the destruction of the neighbouring tissue; you must **immediately inform the healthcare personnel if you have an abnormal sensation on the path of the infused vein.**

Leukaemia has been reported. They can be treated with a curative treatment.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

How to store Epirubicine Mylan 2 mg/ml, solution for infusion?

Before opening: to be stored at a temperature between +2°C and +8°C (refrigerated).

After dilution: the product must be used immediately.

However, the physico-chemical stability of the diluted product in a 0.9 % sodium chloride solution and 5 % glucose solution has been demonstrated for 60 minutes at room temperature.

From a microbiological point of view, the product must 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°C to 8°C.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the vial and box.

This leaflet was approved on: February/2012

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