

Etoposide

MYLAN 20 mg/mL

100mg/
5mL

200mg/
10mL

1 vial
concentrate for solution
for infusion

IV intravenous infusion
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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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Under license from

Mylan S.A.S.

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1. What Etoposide Mylan 20 mg/mL, concentrate for solution for infusion is and what it is used for?

L: ANTICANCER AND IMMUNOSUPPRESSIVE AGENTS.

This medicinal product is recommended for the treatment of certain diseases of the testicles, bronchi, breast and blood. It is usually used in combination with other drugs.

2. Before you use Etoposide Mylan 20 mg/mL, concentrate for solution for infusion?

Do not use Etoposide Mylan 20 mg/mL, concentrate for solution for infusion in the following cases:

- documented previous hypersensitivity to this medicinal product,
- pregnancy or breast-feeding.

In case of doubt, it is essential to ask your doctor or pharmacist for advice.

Take special care with Etoposide Mylan 20 mg/mL, concentrate for solution for infusion

Precautions for use

This medicinal product must be used under close medical supervision. In particular, regular periodic blood counts are essential.

The use of the drug must be evaluated against the risk of myelosuppression in subjects with a white blood cell count below 3,000/mm³ and/or a platelet count below 100,000/mm³.

In renal impairment, the dose should be reduced if creatinine clearance is less than 60 mL/min.

Intravenous infusion only.

This medicinal product contains 248 mg/mL ethanol (alcohol), i.e. up to 3.4 g per dose, equivalent to 90 mL beer, 35 mL wine per dose.

Harmful for those suffering from alcoholism.

To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

The amount of alcohol in this medicinal product may alter the effects of other medicines.

Action to be taken in case of extravasation during intravenous infusion:

- stop the infusion at the first signs of burning
- inject a corticosteroid (100 to 300 mg of hydrocortisone or 4 to 12 mg of dexamethasone) subcutaneously around the lesion,
- apply 1% hydrocortisone ointment around the infiltrated area until the erythema disappears,
- apply dry dressings on the infiltrated area for 24 h.

In case of doubt, do not hesitate to ask your doctor or pharmacist for advice.



Using other medicines

Associations to be taken into consideration:

- cyclosporine: risk of excessive immunosuppression and pseudolymphoma,
- live attenuated vaccines: risk of potentially fatal generalized disease; use an inactivated vaccine if available.

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



Pregnancy - Breast-feeding

Contra-indicated.

Driving and using machines

This medicine can cause nausea and vomiting as well as hypersensitivity reactions associated to hypotension which can disturb the ability to drive or use machines.

The amount of alcohol in this medicinal product may impair your ability to drive or use machines.

Excipients that cause well-known effects:

ethanol (248 mg/mL), benzyl alcohol (30 mg/mL).

3. How to use Etoposide Mylan 20 mg/mL, concentrate for solution for infusion?

Posology

The usual unit dose ranges from 50 to 150 mg/m²/24 hours for 1 to 3 day cycles every 21 to 28 days.

In dose intensification protocols (acute leukemia, malignant lymphoma):

- 40 to 60 mg/kg as a single dose, when etoposide is given with fractionated whole body irradiation,

or

- 40 mg/kg as a single dose or 300 to 400 mg/m² for 3 consecutive days, when etoposide is given in combination with other chemotherapeutic drugs, 3 to 8 days before transplantation, by a 4-hour infusion.

Method and route of administration

Intravenous infusion only.

Like all other nonaqueous solutions for injection, etoposide should be removed from the vial with a glass or polypropylene syringe.

Etoposide can be diluted in 0.9% sodium chloride, 5% glucose or B27 injection.

A diluted solution which is not clear should not be used.

The infusion time should not be less than 60 minutes. In particular, the drug should not be given by direct intravenous injection.

4. Possible side effects

Like all medicines, Etoposide Mylan 20 mg/mL concentrate for solution for infusion, can cause side effects, although not everybody gets them:

- leukopenia and, more rarely, thrombocytopenia, which are reversible, non-cumulative and dose-dependent,
- hypotension may be observed if the intravenous infusion is too rapid,
- anaphylactic reactions (especially cardiopulmonary reactions) have been described occasionally (2% of cases),
- nausea and vomiting occur in approximately one-third of cases,
- alopecia,
- peripheral paresthesias,
- severe mucositis is a dose limiting toxicity.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Etoposide Mylan 20 mg/mL, concentrate for solution for infusion?

Keep out of the reach and sight of children.

Do not use Etoposide Mylan 20 mg/mL, concentrate for solution for infusion after the expiry date which is stated on the label.

The expiry date refers to the last day of that month.

This medicinal product should be stored at a temperature below 25°C.

Do not refrigerate.

After dilution, the solution may be stored for a maximum of 6 hours at a temperature below 25°C.

6. Further information

What Etoposide Mylan 20 mg/mL, concentrate for solution for infusion contains?

The active substance is:

Etoposide..... 20 mg

For 1 mL of concentrate for solution for infusion.

The other components are: anhydrous citric acid, benzyl alcohol, polysorbate 80, macrogol 300, ethanol.

What Etoposide Mylan 20 mg/mL, concentrate for solution for infusion looks like and contents of the pack?

This medicine is a concentrate for solution for infusion. 5 mL vial in box of 1 vial and 10 mL vial in box of 1 vial.

This leaflet was last approved in: June 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