Melphalan 50 mg Powder and Solvent for Solution for Injection/Infusion.

Melphalan is a cytotoxic agent, which falls into the general class of alkylating agents. It is related chemically to the nitrogen mustard compounds and is not cross-resistant to the chlorambucil, cyclophosphamide, and procarbazine. Melphalan has been used in the management of many malignant diseases including leukemia, lymphoma, testicular tumors, breast cancer, and multiple myeloma.

Melphalan 50 mg Powder

Packaged Information for the User

Multiple myeloma—treatment of this disease is usually carried out in conjunction with other cytostatic drugs. The majority of patients treated with melphalan have been included in a number of prospective clinical trials.

Multiple myeloma—melphalan has been used in an oral dosage form in conjunction with other cytostatic drugs, in the treatment of patients with advanced multiple myeloma, who are otherwise in poor medical condition. The standard dosage regimen used in these trials is 5 mg/m² per day for 4 days every 21 days. A dose of 10 mg/m² per day for 4 days every 28 days has also been used. However, this latter regimen is not recommended for patients with significantly impaired renal function. A significant increase in the duration of life-free survival and in the number of patients without evidence of disease was noted in the randomized trial of high-dose melphalan following induction chemotherapy.

Dosage and administration

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If you have more Melphalan than you need
Your doctor may give you an extra amount of the tablets you were given to treat a medical emergency, or for any other reason.

4 Possible side effects
Like all medicines, Melphalan can cause side effects, although not everyone gets them.

• allergic reactions, the signs may include:
  – a skin rash, itching, swelling of the lips, tongue or throat

• damage to the bone marrow
• tissue and organ failure
• problems with the kidneys, liver, heart or lungs

If you get any of the following, talk to your specialist doctor or go to hospital:
• allergic reactions
• allergic reactions to the infusion solution
• allergic reactions to the injection

Your doctor will be prepared for your injection by a healthcare professional. Once injected it should be immediately and must not be stored or refrigerated.

7 Further information
Your doctor

The active ingredient is melphalan. Each Melphalan injection contains 5 mg of melphalan.

The other ingredients are: ethanol 23% and hydrochloric acid. Melphalan is dissolved in hydrochloric acid.

If you have more Melphalan than you need
You should dispose of any other tablets you have left.

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If you do not store Melphalan above 25°C, do not refrigerate. Keep it in the outer carton, protect from light.

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