Melphalan Hydrochloride for Injection

**50 mg**

Rx only

**WARNING**

Melphalan should be administered under the supervision of a qualified pharmacist. Multiple doses of Melphalan Hydrochloride may be used in the treatment of cancer chemotherapeutic agents. Severe bone marrow suppression with resulting infection and bleeding may occur. Close monitoring of vital signs, temperature, and hematologic parameters is essential to determine optimal dosage and to avoid toxicity. Dose adjustment to the start of therapy and prior to each subsequent dose of Melphalan Hydrochloride: platelet count, hemoglobin, and Water for Injection to a total of 10 mL. Melphalan Hydrochloride for Injection is administered in the following tests: white blood cell count, and differential. Thrombocytopenia and/or leukopenia are indicators to withdraw further therapy until the blood counts have sufficiently recovered. Melphalan should be used only if important endpoints such as optimal dose and to avoid toxicity. Dose adjustment on the basis of blood count should be considered.

**CONTRAINDICATIONS**

Melphalan should not be used in patients whose disease has demonstrated prior resistance to this agent. Patients who have demonstrated hypersensitivity to melphalan should not be given the drug.

**WARNINGS**

Melphalan Hydrochloride for Injection may cause local tissue damage and should be considered potentially mutagenic in men. Melphalan produces chromosomal aberrations in vitro and, therefore, should be considered to be potentially mutagenic in men. Melphalan should not be used in patients whose disease has been shown to cause chromatid or chromosome breaks in bone marrow cells of Wistar rats.

**DOSAGE AND ADMINISTRATION**

Pregnancy

Melphalan Hydrochloride for Injection is indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.

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be ascribed of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant.

PRECAUTIONS

General

In all instances where the use of Melphalan Hydrochloride for Injection is considered for chemotherapy, the physician must evaluate the patient as to whether the risk to the patient of the proposed treatment may outweigh the hazards involved. Melphalan should be used with extreme caution in patients with severe hepatic, renal, or cardiac dysfunction. Extensive experience with melphalan suggests that repeated courses should be given since non-linearity in liver enzymes and veno-occlusive disease occur infrequently. Significant hepatic necrosis and liver failure have been reported in patients treated with a single dose of IV melphalan followed by standard supportive care. The potential for acute hepatitis and possibly veno-occlusive disease must be anticipated in patients treated with IV melphalan doses of 0.25 mg/kg or greater. Melphalan should not be given to patients who have recently received a bone marrow transplant.

The development of severe renal failure has been reported in patients treated with a single dose of IV melphalan followed by standard supportive care. This potential is increased in patients with pre-existing renal insufficiency. Melphalan should not be given to patients with pre-existing severe renal insufficiency. Melphalan should not be given to patients with pre-existing severe renal insufficiency. Melphalan should not be given to patients with pre-existing severe renal insufficiency.

The most common side effect is bone marrow suppression leading to anemia, neutropenia, and thrombocytopenia. Severe mucositis, stomatitis, colitis, diarrhea, and hemorrhage of the gastrointestinal tract occur at high doses (>100 mg/m²). Elevations of liver enzymes and veno-occlusive disease occurring infrequently. Significant hepatic necrosis and liver failure have been reported in patients treated with a single dose of IV melphalan followed by standard supportive care. The potential for acute hepatitis and possibly veno-occlusive disease must be anticipated in patients treated with IV melphalan doses of 0.25 mg/kg or greater. Melphalan should not be given to patients who have recently received a bone marrow transplant.

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