



Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, Illinois 60047

Media contact
Matt Kuhn, (847) 550-5751
matt.kuhn@fresenius-kabi.com/us

Fresenius Kabi Melphalan Hydrochloride for Injection Now Available

Generic equivalent to ALKERAN® is latest addition to large oncology portfolio

LAKE ZURICH, III., April 16, 2018 – Fresenius Kabi announced today the immediate availability in the United States of Melphalan Hydrochloride for Injection. Fresenius Kabi Melphalan Hydrochloride for Injection is available as a two-vial kit containing one single dose vial of Melphalan Hydrochloride equivalent to 50 mg Melphalan and one vial of sterile diluent.

Fresenius Kabi is a global health care company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition.

About Melphalan Hydrochloride for Injection

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

Important Safety Information

WARNING

Melphalan should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Severe bone marrow suppression with resulting infection or bleeding may occur. Controlled trials comparing intravenous (IV) to oral melphalan have shown more myelosuppression with the IV formulation. Hypersensitivity reactions, including anaphylaxis, have occurred in approximately 2% of patients who received the IV formulation. Melphalan is leukemogenic in humans. Melphalan produces chromosomal aberrations *in vitro* and *in vivo* and, therefore, should be considered potentially mutagenic in humans.

Melphalan Hydrochloride for Injection 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.

Important Safety Information (Cont'd.)

Melphalan Hydrochloride for Injection may cause local tissue damage should extravasation occur, and consequently it should not be administered by direct injection into a peripheral vein. It is recommended that Melphalan Hydrochloride be administered by injecting slowly into a fast-running IV infusion via an injection port, or via a central venous line.

In all instances where the use of Melphalan Hydrochloride for Injection is considered for chemotherapy, the physician must evaluate the need and usefulness of the drug against the risk of adverse events. Melphalan Hydrochloride for Injection should be used with extreme caution in patients whose bone marrow reserve may have been compromised by prior irradiation or chemotherapy or whose marrow function is recovering from previous cytotoxic therapy.

Administration of live vaccines to immuno-compromised patients should be avoided.

The following information on adverse reactions is based on data from both oral and IV administration of Melphalan Hydrochloride as a single agent, using several different dose schedules for treatment of a wide variety of malignancies.

The most common side effect is bone marrow suppression leading to leukopenia, thrombocytopenia, and anemia. White blood cell count and platelet count nadirs usually occur 2 to 3 weeks after treatment, with recovery in 4 to 5 weeks after treatment. Irreversible bone marrow failure has been reported. Gastrointestinal disturbances such as nausea and vomiting, diarrhea, and oral ulceration occur infrequently. Hepatic disorders ranging from abnormal liver function tests to clinical manifestations such as hepatitis and jaundice have been reported. Hepatic veno-occlusive disease has been reported.

Other reported adverse reactions include skin hypersensitivity, skin ulceration at injection site, skin necrosis rarely requiring skin grafting, maculopapular rashes, vasculitis, alopecia, hemolytic anemia, allergic reaction, pulmonary fibrosis (including fatal outcomes), and interstitial pneumonitis. Temporary significant elevation of the blood urea has been seen in the early stages of therapy in patients with renal damage. Subjective and transient sensation of warmth and/or tingling.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA at 1-800-551-7176 option 5 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. This important safety information does not include all the information needed to use MELPHALAN HYDROCHLORIDE FOR INJECTION safely and effectively. Please click on <https://tinyurl.com/yd4wms5r> for the full prescribing information for MELPHALAN HYDROCHLORIDE FOR INJECTION, including BOXED WARNING, or visit www.fresenius-kabi.com/us.

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About Fresenius Kabi

Fresenius Kabi (www.fresenius-kabi.com/us) is a global health care company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. The company's U.S. headquarters is in Lake Zurich, Illinois. The company's global headquarters is in Bad Homburg, Germany.

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