

Alkeran[®] (melphalan) – First-time generic

- On June 26, 2017, Alvogen launched an <u>AB-rated</u> generic version of ApoPharma's <u>Alkeran</u> (<u>melphalan</u>) 2 mg tablets.
- Alkeran is indicated for the palliative treatment of multiple myeloma and for the palliation of nonresectable epithelial carcinoma of the ovary.
- Melphalan is also generically available as a <u>50 mg vial</u> for intravenous infusion, and as a branded propylene glycol-free formulation (<u>Evomela[®]</u>).
 - Intravenous melphalan and Evomela are indicated for the palliative treatment of patients with multiple myeloma for whom oral therapy is not appropriate.
 - Evomela is also indicated for use as a high-dose conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation in patients with multiple myeloma.
- Alkeran carries a boxed warning stating that it 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.
 - Alkeran is leukemogenic in humans.
 - Alkeran produces chromosomal aberrations *in vitro* and *in vivo* and, therefore, should be considered potentially mutagenic in humans.



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