Busulfan
Injection

60 mg per 10 mL | NDC 70860-216-10

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- **BIG, BOLD AND BRIGHT —
TO HELP YOU SEE IT, SAY IT AND PICK IT RIGHT**
- **DIFFERENTIATION IN EVERY LABEL,
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PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING, FOR BUSULFAN INJECTION, ENCLOSED.

THE NEXT GENERATION OF PHARMACY INNOVATION

Busulfan

Injection

60 mg

NDC 70860-216-10
60 mg per 10 mL

DESCRIPTION	Glass Vial
CONCENTRATION	6 mg per mL
CLOSURE	20 mm
UNIT OF SALE	8 vials
BAR CODED	Yes

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Our proprietary, differentiated and highly-visible label designs can assist pharmacists in accurate medication selection.

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BUSULFAN Injection

INDICATION AND USAGE

- Busulfan injection is indicated for use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia.

IMPORTANT SAFETY INFORMATION

WARNING: MYELOSUPPRESSION

BUSULFAN INJECTION CAUSES SEVERE AND PROLONGED MYELOSUPPRESSION AT THE RECOMMENDED DOSAGE. HEMATOPOIETIC PROGENITOR CELL TRANSPLANTATION IS REQUIRED TO PREVENT POTENTIALLY FATAL COMPLICATIONS OF THE PROLONGED MYELOSUPPRESSION

CONTRAINDICATIONS

- Busulfan is contraindicated in patients with a history of hypersensitivity to any of its components.

WARNINGS and PRECAUTIONS

- **Myelosuppression:** The most frequent serious consequence of treatment with busulfan at the recommended dose and schedule is prolonged myelosuppression, occurring in all patients (100%). Severe granulocytopenia, thrombocytopenia, anemia, or any combination thereof may develop. Hematopoietic progenitor cell transplantation is required to prevent potentially fatal complications. Monitor complete blood counts, including white blood cell differentials, and quantitative platelet counts daily during treatment. Use antibiotic therapy and platelet and red blood cell support when medically indicated.
- **Seizures:** Seizures have been reported in patients receiving high-dose oral busulfan at doses producing plasma drug levels similar to those achieved following the recommended dosage of Busulfan Injection. Initiate phenytoin therapy or any other alternative anti-convulsant prophylactic therapy (e.g., benzodiazepines, valproic acid or levetiracetam) prior to Busulfan Injection treatment. Use caution when administering the recommended dose of Busulfan Injection to patients with a history of a seizure disorder or head trauma or who are receiving other potentially epileptogenic drugs.
- **Hepatic Veno-Occlusive Disease (HVOD):** High busulfan area under the plasma concentration vs. time curve (AUC) values (greater than 1,500 μM•min) may be associated with an increased risk of developing HVOD. Patients who have received prior radiation therapy, greater than or equal to three cycles of chemotherapy, or a prior progenitor cell transplant may be at an increased risk of developing HVOD. Monitor serum transaminases, alkaline phosphatase, and bilirubin daily through BMT Day +28 to detect hepatotoxicity, which may herald the onset of HVOD.
- **Embryo-fetal Toxicity:** Busulfan Injection can cause fetal harm when administered to a pregnant woman based on animal data. Advise pregnant women of the potential risk to a fetus. Busulfan Injection may damage spermatozoa and testicular tissue. Advise females and males of reproductive potential to use effective contraception during and after treatment with Busulfan Injection.
- **Cardiac Tamponade:** Cardiac tamponade has been reported in pediatric patients with thalassemia who received high doses of oral busulfan and cyclophosphamide as the preparatory regimen for hematopoietic progenitor cell transplantation. Abdominal pain and vomiting preceded the tamponade in most patients. Monitor for signs and symptoms, promptly evaluate and treat if cardiac tamponade is suspected.
- **Bronchopulmonary Dysplasia:** Bronchopulmonary dysplasia with pulmonary fibrosis is a rare but serious complication following chronic busulfan therapy. The average onset of symptoms is 4 years after therapy (range 4 months to 10 years).
- **Cellular Dysplasia:** Busulfan Injection may cause cellular dysplasia in many organs. The resulting cytologic abnormalities may be severe enough to cause difficulty in the interpretation of exfoliative cytologic examinations of the lungs, bladder, breast and the uterine cervix.
- **Lactation:** Advise women to discontinue breastfeeding because of the potential for tumorigenicity shown for busulfan in animal and human studies.

ADVERSE REACTIONS

- The most common adverse reactions (incidence greater than 60%) were myelosuppression, nausea, stomatitis, vomiting, anorexia, diarrhea, insomnia, fever, headache, hypomagnesemia, abdominal pain, anxiety, hyperglycemia, and hypokalemia.

OVERDOSAGE

- There is no known antidote to Busulfan Injection other than hematopoietic progenitor cell transplantation. In the absence of hematopoietic progenitor cell transplantation, the recommended dosage for Busulfan Injection would constitute an overdose of busulfan. The principal toxic effect is profound bone marrow hypoplasia/aplasia and pancytopenia, but the central nervous system, liver, lungs, and gastrointestinal tract may be affected. Monitor hematologic status closely and institute vigorous supportive measures as medically indicated. Dialysis should be considered in the case of overdose.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for BUSULFAN Injection.