IVBusulfex®
(busulfan) Injection

Exactly how you want to begin

Dear Pharmacist:

We are pleased to announce that IV Busulfex is now available in a new single-use clear-glass 10-mL vial. We believe you and your colleagues will welcome this change as the new vial configuration offers added ease of preparation and convenience in addition to a longer shelf life.

Please note that the formulation has not changed.

IV Busulfex continues to offer controlled myeloblation allowing HSCT specialists to target results appropriately for each individual patient.[1] The new vial configuration offers:

- **No filtration required**
  - Decreased preparation time
- **No need to break glass top**
  - Fewer preparation steps
- **Smaller package**
  - Less storage space required
- **Longer shelf life**
  - Now 24 months

Enclosed is the new vial product fact sheet that outlines the specifications for your pharmacy's reference. Thank you for noting this important change.

For more information about IV Busulfex, please contact PDL BioPharma Medical Information:

Tel: (866) 829-5300 option 3
Fax: (510) 574-1496
E-mail: medinfo@pdl.com

Sincerely,

Stacie Speelman
Associate Product Manager

Bookmark
IVBUSULFEX.com

Learn about clinical data, dosing, administration, and other important topics by visiting www.IVBUSULFEX.com.

For use in combination with cyclophosphamide as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation (HSCT) for chronic myelogenous leukemia (CML)

Important Safety Information At the recommended dosage, IV Busulfex produced profound myelosuppression in all patients (ie, severe granulocytopenia, thrombocytopenia, anemia, or a combination thereof). Frequent complete blood counts should be monitored during treatment and until recovery. Hepatic veno-occlusive disease was diagnosed in 5/61 patients and was fatal in 2/5 cases. Anticonvulsant prophylactic therapy should be administered prior to treatment. Caution should be exercised in patients with a history of seizure disorder or head trauma or who are receiving other potentially epileptogenic drugs. Women of childbearing potential should be advised to avoid becoming pregnant as busulfan may cause fetal harm. The most common nonhematologic adverse events were nausea (92% mild or moderate, 7% severe), stomatitis (71% grade 1–2, 26% grade 3–4), and vomiting (95% mild or moderate).

WARNING: BUSULFEX (busulfan) Injection is a potent cytotoxic drug that causes profound myelosuppression at the recommended dosage. It should be administered under the supervision of a qualified physician who is experienced in allogeneic hematopoietic stem cell transplantation, the use of cancer chemotherapeutic drugs, and the management of patients with severe pancytopenia. Appropriate management of therapy and complications is only possible when adequate diagnostic and treatment facilities are readily available. SEE "WARNINGS" SECTION OF FULL PRESCRIBING INFORMATION FOR INFORMATION REGARDING BUSULFAN-INDUCED PANCYTOPENIA IN HUMANS.

Please see accompanying full prescribing information.

1. IV Busulfex (busulfan) Injection full prescribing information. PDL BioPharma, Inc. 2007.

PDL BioPharma
Redwood City, CA 94063

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Exactly how you want to begin

NEW VIAL

Enhanced convenience and ease of preparation

- **No filtration required**
  Decreased preparation time
- **No need to break glass top**
  Fewer preparation steps
- **Smaller package**
  Less storage space required
- **Longer shelf life**
  Now 24 months

New vial. Same formulation.

IV Busulfex offers controlled myeloablation, allowing HSCT specialists to target results appropriately for each individual patient.[1]

For more information, visit
www.IVBUSULFEX.com

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NEW VIAL

Pharmacy information

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How supplied

IV Busulfex is supplied as a clear, colorless, sterile solution in 10-mL single-use glass vials each containing 60 mg of busulfan at a concentration of 6 mg/mL for intravenous use. IV Busulfex is packaged in a tray pack of 8 vials.

The new vials are made of Wheaton clear 10-mL, 13-mm, Type 1 Flint Tubing with Teflon-coated stoppers containing a 13-mm flip-off seal and metal crimp.

Preparation, storage, and stability

Filtration	Shelf Carton Size	Unit Carton Size	Stability
Not required	**2.7" x 2.9" x 5.8" (44" area)**	**2.5" x 1.4" x 1.4" (4.7" area)**	**24-month expiry period**

Unopened vials of BUSULFEX must be refrigerated at conditions between 2°–8°C (36°–46°F).

Formulation

Ingredient	Quantity per vial (10 mL)	Function
Busulfan	**60 mg**	**Drug substance**
Polyethylene glycol 400 (Macrogol 400)	**6.7 mL**	**Vehicle**
Dimethylacetamide	**3.3 mL**	**Vehicle**

Ordering

Packaging	NDC
Shelf carton (8 unit cartons per shelf carton)	**67286-0054-8**

PI

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Please see important safety information and black box warning on reverse side.
Please see accompanying full prescribing information.

Manufactured by: Ben Venue Labs, Inc. Bedford, OH 44146

PDL BioPharma
Redwood City, CA 94063