



March 18, 2011

Dear Director of Pharmacy,

Thank you for your support of the ampoule version of IV BUSULFEX[®] (busulfan) Injection, 6 mg/mL, NDC code 59148-071-91. This previously approved and marketed version will be available, as we work to resolve issues related to the supply of vials with our contract manufacturer over the next several weeks.

The ampoules are provided with a sterile GE[®] 5 micron pore size, 25 mm filter size with acrylic housing and Nylon filter membrane. In accordance with pharmacy practices, filter BUSULFEX using the 5 micron syringe filter provided with each package, using one filter per ampoule.

USE OF FILTERS OTHER THAN THE SPECIFIC TYPE INCLUDED IN THIS PACKAGE WITH EACH AMPOULE IS NOT RECOMMENDED. DO NOT USE POLYCARBONATE SYRINGES OR POLYCARBONATE FILTER NEEDLES WITH BUSULFEX.

We want to bring to your attention that your upcoming orders may contain the version of the package insert that was approved at the time of packaging. For your reference, we are also enclosing a copy of the most current package insert that contains an updated Post Marketing Experience section as follows:

Post-Marketing Experience: The following adverse reactions (reported as MedRA terms) have been identified during post-approval use of BUSULFEX (busulfan) Injection: febrile neutropenia; tumor lysis syndrome; thrombotic micro-angiopathy (TMA); severe bacterial, viral (e.g., cytomegalovirus viraemia) and fungal infections; and sepsis. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to establish a causal relationship to drug exposure.

Please call our medical information hotline at 1-800-438-6141 with any inquiries. The hotline operates 24 hours each day, seven days per week.

Adverse event information may be reported to FDA's MedWatch Reporting System by:

- Phone at 1-800-FDA-1088 (1-800-332-1088)
- Facsimile at 1-800-FDA-0178 (1-800-332-0178)
- Mail using FDA Form 3500 located at <http://www.fda.gov/medwatch>

Sincerely,

Dario Mirski, Vice President, Medical Affairs

Enclosure

Please see accompanying FULL PRESCRIBING INFORMATION, including **Boxed WARNING**.

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