

**Notice to Hospitals**  
**Health Canada Endorsed Important Safety Information on**  
**AMSA PD Inj 50 mg/mL**



2014-08-29

Version 1.0

Dear Healthcare Professional,

Please distribute to relevant Departments: Pharmacy, Paediatrics, Oncology, Hematology, Internal Medicine, Nursing, other Departments as required and other involved professional staff and **post this notice** in your institution.

**Subject: Potential low risk of microbial contamination of AMSA PD Inj 50 mg/mL (amsacrine injection) DIN: 00582212**

ERFA Canada 2012 Inc. in consultation with Health Canada is informing you of a potential but very low risk of infection with AMSA PD Inj 50 mg/mL (amsacrine injection) AMSA PD is indicated for the induction of remission in acute adult leukemia refractory to conventional therapy.

Due to a manufacturing issue, a very low risk of microbial contamination of the product exists which could lead to infection. A recall has not been implemented given that the risk of contamination is minimal, this drug is medically necessary for a small number of patients and because there is limited supply of product available. However, it is advised that healthcare professionals should determine if the benefit of treatment with AMSA PD Inj 50 mg/mL outweighs the potential but very low risk of infection related to use of this product.

- Due to a manufacturing issue, AMSA PD Inj 50 mg/mL has a very low risk of microbial contamination that could lead to infection.
- Erfa Canada 2012 Inc. recommends that the risk of contamination could be further minimized by the use of Sartorius sterile filters Minisart SRP (PTFE) 0.2 µm, 15 mm prior to transferring AMSA PD Inj 50 mg/mL to the diluents. (Please see attached Annex I). These filters will be provided by ERFA Canada 2012 Inc.
- Healthcare professionals are advised to monitor their patients treated with AMSA PD Inj 50 mg/mL for any signs or symptoms of infection.

ERFA Canada 2012 Inc. is advising healthcare professionals of a possible and eventual lack of supply of AMSA PD Inj 50 mg/mL until the manufacturing issues are resolved. Please consult [www.drugshortages.ca](http://www.drugshortages.ca) for updated shortage and resupply information.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-market adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any cases of serious infection or other serious or unexpected adverse reactions in patients receiving AMSA PD Inj 50 mg/mL should be reported to ERFA CANADA 2012 Inc. or Health Canada.

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**To correct your mailing address or fax number, contact ERFA Canada 2012 Inc.**

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345, or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:  
Lead Directorate: Health Products and Food Branch Inspectorate  
E-mail: DCVIU\_UVECM@hc-sc.gc.ca  
Telephone: 1-800-267-9675  
Fax: 1-613-946-5636

***Original signed by***



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## **ANNEX I**

### **METHOD OF PREPARATION**

#### Step One:

Each ampoule contains 75 mg (1.5 ml) of AMSA PD for infusion. **Filter the solution with sterile Minisart SRP 15 mm (PFTE) 0.2 µm filter provided with the product.** Aseptically transfer 1.5 ml from the ampoule to the vial which contains 13.5 ml of L-lactic acid diluent (use only the diluent provided). The resulting orange-red solution is the STOCK SOLUTION which contains 5 mg AMSA PD per ml. It is preferable to use glass syringes for step one, however, plastic syringes can be used, providing that AMSA PD remains in the syringes for no longer than 15 minutes. The stock solution is chemically stable for 24 hours at room temperature when protected from exposure to direct sunlight. Since this solution does not contain a preservative, any unused portion should be discarded.

*Please refer to the Canadian Product Monograph (August 16, 2005) for further details on how to prepare AMSA PD Inj.*