August 17, 2022

Important Prescribing Information

Subject: Fludarabine Phosphate Injection, USP, solution to Address Supply Shortage

Dear Health Care Provider:

To address the ongoing shortage, Areva has coordinated with FDA to allow release of a temporary supply of Fludarabine Phosphate Injection 50mg per 2mL (25 mg/mL) Single Dose vials manufactured with active pharmaceutical ingredient (API) from a supplier that is not currently approved under Areva's ANDA (090724). The lots for this temporary supply of Fludarabine Phosphate Injection 50mg per 2mL (25 mg/mL) Single Dose vials have undergone Areva's internal review for quality and safety, and Areva will continue to work with its new API supplier and FDA to seek approval of the API supplier.

Effective immediately, and during this temporary period, Areva will offer the following:

Product Name and Description	**Size**	**NDC**	**Lot Number**
Fludarabine Phosphate Injection, USP 50 mg/2 mL	5 mL glass vial	59923-604-02	N2200752

Fludarabine Phosphate Injection is indicated for the treatment of adult patients with B-cell chronic lymphocytic leukemia (CLL) who have not responded to or whose disease has progressed during treatment with at least one standard alkylating-agent containing regimen.

There is no change in the indication, dosing and administration, or safety information as described in the approved package insert. There is no change to how healthcare professionals will prescribe or dispense Fludarabine Phosphate Injection.

Please refer to the FDA-approved package insert for the full prescribing information of Fludarabine Phosphate Injection.

Reporting Adverse Events

Healthcare providers should report quality problems and all adverse events associated with the use of Fludarabine to Areva at 1-855-853-4760 or fax 1-812-951-1099.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

To place an order, please contact Areva's Customer Service by calling 1-812-399-3599.

If you have questions about the information contained in this letter or the use of the product, please contact Areva at 1-855-853-4760.

Sincerely,

Victor Swaminathan

Victor Swaminathan, R.Ph.
Director of Supply Chain Management
Areva Pharmaceuticals, Inc.