



Fera Pharmaceuticals, LLC
134 Birch Hill Road
Locust Valley, New York 11560

April 17, 2023

IMPORTANT DRUG INFORMATION

Subject: Shelf-Life Extension for Phospholine Iodide® 0.125%, for ophthalmic solution, 6.25 mg/5 mL vial

Dear Customer and Healthcare Provider,

To prevent a supply disruption during the market shortage, the U.S. Food and Drug Administration (FDA) approved a shelf-life extension for Phospholine Iodide (echothiophate iodide for ophthalmic solution), 0.125%, from 36 months to 42 months based on available stability data, when stored according to labeled storage and handling requirements:

Product Description	NDC	Lot/ Batch #	Expiration Date (Labeled)	Extended Expiration Date
Phospholine Iodide Lyophilized 6.25 mg/5 mL vial	48102-053-05	1850-140A	05/2023	11/2023

You may have already received Phospholine Iodide labeled with the 36-month shelf life and an expiration date of May 2023. **Please do not discard this Phospholine Iodide as it can continue to be used for additional 6 months until November 2023.**

The FDA is not requiring or recommending that the Phospholine Iodide remaining from the above lot be relabeled with the new expiration date. FERA is the sole supplier of Phospholine Iodide in the US. Phospholine Iodide is indicated for treatment of increased intraocular pressure and accommodative esotropia.

For additional questions about the information contained in this letter, please contact FERA at (516) 277-1449 or visit the FDA website at www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages.

Healthcare providers and patients are encouraged to report adverse events in patients using Phospholine Iodide to FERA at 1-414-434-6604.

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).

We appreciate your immediate attention to this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Michelle Kim".

Michelle Kim, PharmD.
Sr. Director, Regulatory Affairs