

July 07, 2021

URGENT: Important Drug Information

Notification Regarding Shelf Life Extension for Phospholine Iodide[®].

Dear Customer and Healthcare Provider,

Pfizer is committed to providing product updates so that Healthcare Providers can plan for patient care. The intent of this letter is to notify you that on July 6, 2021, the U.S. Food and Drug Administration (FDA) approved a shelf life extension for Phospholine Iodide[®] (echothiophate iodide for ophthalmic solution) from 24 months to 36 months.

Phospholine lodide has been discontinued by Pfizer; however, the shelf life extension has made additional limited inventory of product available.

You may have already received Phospholine lodide labeled with the 24-month shelf life. Pfizer Inc. is writing to let you know that Phospholine lodide has an additional 12 months of shelf life (increased from 24 months to 36 months) when stored according to labeled storage and handling requirements, and that this extension has been approved by FDA. Please do not discard this Phospholine lodide as it can continue to be used for an additional 12 months beyond the labeled date, as detailed in the table below.

Product Description	NDC	LOT/batch #	Expiration Date (Labeled)	Extended Use Date
Phospholine lodide Lyophilized 6.25 mg/vial	0046-1065-05	1850139	06/2021	06/2022

The FDA is not requiring or recommending that the Phospholine lodide remaining from the above lot be relabeled with the new use dates but is allowing for its continued use.

Please note that Phospholine lodide remains available with limited inventory levels and will be drop shipped while supplies last. To access this product, please contact Pfizer Customer Service at 1-800-533-4535, option 4.

Phospholine lodide is approved to treat increased intraocular pressure and accommodative esotropia. The full Prescribing Information for Phospholine lodide can be found

at: https://www.pfizer.com/products/product-detail/phospholine_iodide

For additional medical questions on Phosphine lodide, please contact Pfizer Medical Information 1-800-438-1985. Healthcare providers are encouraged to report adverse events, including product defects, by contacting Pfizer at 1-800-438-1985 or by contacting the FDA at <u>http://www.fda.gov/Safety/MedWatch</u> or by calling 1-800-FDA-1088.

We appreciate your immediate attention to this matter. Sincerely,

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Olga Tarasova, M.D., MBA US Medical Affairs Pfizer

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