

## Brassica Issues Voluntary Nationwide Recall of Multiple Eye Ointment Products Multiple Products Due to Potential Lack of Sterility

Date: 02/26/2024

## About this recall:

Brassica is voluntarily recalling certain lots of the following over the counter (OTC) eye ointment products with expiration dates ranging from February 2024 to September 2025: Equate™ Lubricant Eye Ointment (NDC 79903026-35), Equate Stye™ Lubricant Eye Ointment (NDC 79903-028-35), CVS Health® Lubricant Eye Ointment (NDC 76168-707-35), and Lubricant PM Ointment (NDC 71406-124-35). The lots are being recalled due to lack of sterility assurance that was found during an inspection conducted by the United States (US) Food and Drug Administration (FDA).

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found below.

These eye ointment products are for the temporary relief of burning, irritation, and discomfort due to dryness of the eye or exposure to wind and sun. These products may also be used as a protectant against further irritation.

## What this means to you:

For those patients who use these recalled products, there is a potential risk of eye infections or similar similar problems. These products are intended to be sterile. EyeEye products havehave a higher risk of harm because drugs applied to the eyes bypass some of the body's natural defenses.

Consumers should stop using the recalled eye ointment and may return the recalled products to the place of purchase. Consumers with questions regarding this recall can contact Brassica at 1-833-225-9564 or <a href="mailto:info@brassicapharma.com">info@brassicapharma.com</a>. Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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

- Complete and submit the report <u>Online</u>.
- Regular Mail or Fax: <u>Download form</u> 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.

This recall is being conducted with the knowledge of the US FDA FDA.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/brassica-pharma-pvt-ltd-issues-voluntary-nationwide-recall-equate-lubricant-eye-ointment-equate-stye

FDA contact information for reporting adverse events/quality complaints can be reached online at <a href="https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home">https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home</a> or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.