

# Important Drug Recall Notice

## TO ALL PARTICIPATING PHARMACIES

### Circular Letter MC24-010-CG February 29, 2024

FDA announced that Brassica Pharma Pvt. Ltd. is voluntarily recalling Eye Ointment products listed in the table below with expiration date ranging from February 2024 to September 2025. The products are being recalled due to lack of sterility assurance at the facility noted during an inspection conducted by the Food and Drug Administration (FDA).

### RECOMMENDATIONS

1. Brassica Pharma Pvt. Ltd. Is notifying its distributors AACE Pharmaceuticals Inc and its retailers Walmart and CVS. These distributors shall be further notifying the wholesalers and retailers via mail of this voluntary recall and arranging for return of all impacted products listed above.
2. Consumers, distributors and retailers that have any product which is being recalled should cease distribution of the product. Consumers should stop using the recalled Eye Ointment and may return any of the above listed products to the place of purchase.
3. Consumers with questions regarding this recall can contact Brassica Pharma Pvt. Ltd. at +1 833-225-9564 or [info@brassicapharma.com](mailto:info@brassicapharma.com).
4. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
5. Review your inventory to identify existence of recalled products.
6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

### MC-Rx Pharmacy Services Department

**Brassica Pharma Pvt. Ltd. Issues Voluntary Nationwide Recall of Equate Lubricant Eye Ointment, Equate Styelubricant Eye Ointment, CVS Health Lubricant Eye Ointment, Lubricant PM Ointment Due to Potential Lack of Sterility**

**SUMMARY:**

<b>Company Announcement Date:</b>	February 22, 2024
<b>FDA Publish Date:</b>	February 26, 2024
<b>Product Type:</b>	Drugs
<b>Reason for Announcement:</b>	Due to Potential Lack of Sterility Assurance.
<b>Company Name:</b>	Brassica Pharma Pvt. Ltd.
<b>Brand Name:</b>	Multiple brands
<b>Product Description:</b>	Eye ointment products

**COMPANY ANNOUNCEMENT**

**FOR IMMEDIATE RELEASE** – 12 February, 2024 – Thane, Maharashtra, India, Brassica Pharma Pvt. Ltd. is voluntarily recalling Eye Ointment products listed in the table below with expiration date ranging from February 2024 to September 2025. The products are being recalled due to lack of sterility assurance at the facility noted during an inspection conducted by the Food and Drug Administration (FDA).

Risk Statement: For those patients who use these products, there is a potential risk of eye infections or related harm. These products are intended to be sterile. Ophthalmic drug products pose a potential heightened risk of harm to users because drugs applied to the eyes bypass some of the body’s natural defenses. To date, Brassica Pharma Pvt. Ltd. has not received any reports of adverse events up to 16th February 2024 related to this recall.

Product Name	Package Description	Brand Name	NDC	Lot# Exp Date	Exp Date
Equate Lubricant Eye Ointment (Mineral Oil 42.5%, White)	3.5 gram tube, packaged in cardboard box with UPC Code 681131395298	Equate	79903-026-35	A2E01	Apr-24
				A2L05	Nov-24

Product Name	Package Description	Brand Name	NDC	Lot# Exp Date	Exp Date
Petrolatum 57.3%, Lanolin Alcohols)				A3B01	Jan-25
				A3C01	Feb-25
				A3H05	Jul-25
Equate Styelubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%, Microcrystalline Wax, Stearic Acid, Wheat Germ Oil)	3.5 gram tube, packaged in cardboard box with UPC Code 681131395304	Equate	79903-028-35	A2D08	Mar-24
				A2F02	May-24
				A2I03	Aug-24
				A2L03	Nov-24
				A2L04	Nov-24
				A3C03	Feb-25
				A3C05	Feb-25
				A3H01	Jul-25
				A3H03	Jul-25
CVS Health Lubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%, Microcrystalline Wax, Stearic Acid Wheat Germ Oil	3.5 gram tube, packaged in cardboard box with UPC Code 050428634141	CVS Health	76168-707-35	A2F03	May-24
				A2I02	Aug-24
				A2L02	Nov-24
				A3C04	Feb-25
				A3H04	Jul-25
Lubricant PM Ointment	3.5 gram tube, packaged in cardboard box with UPC Code 371406124356	AACE Pharmaceuticals	71406-124-35	A2G01	Jun-24
				A2G02	Jun-24

Product Name	Package Description	Brand Name	NDC	Lot# Exp Date	Exp Date
				A3F08	May-25
				A3F09	May-25
				A3J17	Sep-25
				A3J18	Sep-25

These products were distributed nationwide to wholesalers, retailers, and via the product distributor, Walmart, CVS and AACE Pharmaceuticals Inc.

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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 **Online**
- Regular Mail or Fax: **Download form** 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**