

# Brassica Pharma Pvt. Ltd. Issues Voluntary Nationwide Recall Due to potential lack of sterility

Brassica Pharma Pvt. Ltd. Issues Voluntary Nationwide Recall of Equate Lubricant Eye Ointment, Equate Styel Lubricant Eye Ointment, CVS Health Lubricant Eye Ointment, Lubricant PM Ointment Due to potential lack of sterility

Product Name	Package Description	Brand Name	NDC	Lot #/ Exp Date	Exp Date
Equate Lubricant Eye Ointment (Mineral Oil 42.5%, White Petrolatum 57.3%, Lanolin Alcohols)	3.5 gram tube, packaged in cardboard box with UPC Code 681131395298	Equate	79903-026-35	A2E01	Apr-24
				A2L05	Nov-24
				A3B01	Jan-25
				A3C01	Feb-25
				A3H05	Jul-25
Equate Styel 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 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
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
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
				A3F08	May-25
				A3F09	May-25
				A3J17	Sep-25
				A3J18	Sep-25

Mumbai, Maharashtra Feb 22, 2024 ([Issuewire.com](http://Issuewire.com)) - Company Contact:

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**Brassica Pharma Pvt. Ltd.** is voluntarily recalling Eye Ointment products listed in the table below with expiration dates ranging from February 2024 to September 2025. The **products** are being recalled due to a 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 potentially 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 upto 16th

February 2024 related to this recall.

Product Name: Equate Lubricant Eye Ointment (Mineral Oil 42.5%, White Petrolatum 57.3%, Lanolin Alcohols)

Package Description: 3.5-gram tube, packaged in a cardboard box with UPC Code 681131395298

Brand Name: Equate

NDC: 79903-026-35

Lot #/ Exp Date: A2E01- Apr-24; A2L05-Nov-24; A3B01- Jan-25; A3C01- Feb-25; A3H05- Jul-25

Product Name: Equate Styel Lubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%, Microcrystalline Wax, Stearic Acid, Wheat Germ Oil)

Package Description: 3.5-gram tube, packaged in a cardboard box with UPC Code 681131395304

Brand Name: Equate

NDC: 79903-028-35

Lot #/ Exp Date: A2D08-Mar-24; A2F02-May-24; A2I03Aug-24; A2L03-Nov-24; A2L04-Nov-24; A3C03-Feb-25; A3C05-Feb -25; A3H01-Jul-25; A3H03-Jul-25

Product Name: CVS Health Lubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%, Microcrystalline Wax, Stearic Acid Wheat Germ Oil)

Package Description: 3.5-gram tube, packaged in a cardboard box with UPC Code 050428634141

Brand Name: CVS Health

NDC: 76168-707-35

Lot #/ Exp Date:

Product Name: Lubricant PM Ointment

Package Description: 3.5-gram tube, packaged in a cardboard box with UPC Code 371406124356

Brand Name: AACE Pharmaceuticals

NDC: 71406-124-35

Lot #/ Exp Date: A2F03-May-24; A2I02-Aug-24; A2L02-Nov-24; A3C04-Feb-25; A3H04-Jul-25

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

**Brassica Pharma Pvt. Ltd.** Is notifying its distributors AACE Pharmaceuticals Inc. and its retailers

Walmart and CVS. These distributors shall further notify the wholesalers and retailers **via mail of this voluntary recall and arrange for the return of all impacted products listed above.** Consumers, distributors, and retailers that have any product that 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.

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). 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.

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:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download the form [www.fda.gov/MedWatch/getforms.htm](http://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.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.



## Media Contact

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Source : Brassica Pharma

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