

Brassica Pharma - Recall of eye ointment products

- On February 26, 2024, <u>Brassica Pharma announced</u> a consumer level recall of multiple lots of eye
 ointment products (see chart below) because of potential lack of sterility noted during an inspection
 conducted by the FDA.
- The eye ointment products were distributed nationwide.

Product Description	NDC#	Lot # (Expiration Date)
Equate Lubricant Eye Ointment (Mineral Oil 42.5%, White Petrolatum 57.3%, Lanolin Alcohols) 3.5 gram tube	79903-026-35	A2E01 (Apr-24); A2L05 (Nov-24); A3B01 (Jan-25); A3C01 (Feb-25); A3H05 (Jul-25)
Equate Stye Lubricant Eye Ointment (Mineral Oil 31.9%, White Petrolatum 57.7%, Microcrystalline Wax, Stearic Acid, Wheat Germ Oil) 3.5 gram tube	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	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	71406-124-35	A2G01 (Jun-24); A2G02 (Jun-24); A3F08 (May-25); A3F09 (May-25); A3J17 (Sep-25); A3J18 (Sep-25)

- These eye ointments are used to temporarily relieve burning and irritation of the eye and discomfort due to dryness of the eye or exposure to wind or sun, and as a protectant against further irritation.
- 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 has not received any reports of adverse events related to this recall.

- Anyone with the affected lots on hand should stop distribution and return product. Patients who have bottles from the recalled lots of eye ointments should contact their pharmacy.
- Contact Brassica at 1-833-225-9564 or by email at <u>info@brassicapharma.com</u> for questions regarding this recall.



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