Alcon Issues Voluntary Nationwide Recall of One Lot of Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go

Date: 12/23/2024

At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls .

About this recall:
Alcon is voluntarily recalling one lot of Systane Lubricant Eye Drops Ultra PF, Single Vials On-the-Go, 25-count to the consumer level. Following a consumer complaint of foreign material inside a sealed single use vial, the manufacturer determined the foreign material was fungal contamination.

Systane Lubricant Eye Drops are used for the temporary relief of burning and irritation in individuals experiencing dry eye symptoms. Recalled product is packaged in a cardboard carton containing 25 sterile, single-use plastic vials of preservative free solution. The recalled NDC is 00065-1432-06, and the recalled lot is 10101 (expiration date 09/2025).

What this means to you:
Fungal contamination of an eye product could potentially cause eye infections. If an infection occurs, it could lead to vision loss, and very rarely, life-threatening infections in patients with weakened immune systems. To date, Alcon has not received any reports of adverse events related to this recall.

Consumers that have the recalled product should stop use immediately and return to the place of purchase for a replacement or refund. Consumers with questions regarding this recall can contact Alcon at 1-800-241-5999 between 7:30 am and 6:00 pm Central, Monday to Friday. Consumers should contact their health care provider if they have experienced any problems that may be related to 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.
- 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.

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

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alcon-laboratories-issues-voluntary-nationwide-recall-one-1-lot-systane-lubricant-eye-drops-ultra-pf

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