Endo Issues Voluntary Nationwide Recall of Adrenalin® Chloride Solution (epinephrine nasal solution) Due to Potential for Administration Errors

Date: 12/20/2024

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:
Endo is voluntarily recalling **all lots within expiry** of Adrenalin Chloride Solution (epinephrine ***nasal solution***) 30 mg/30 mL (1 mg/mL) 30 mL vials (NDC 42023-0103-01) to the consumer level. The product pre-dates the 1938 Federal Food, Drug & Cosmetic Act and was never submitted for FDA approval. Therefore, it is an unapproved drug for which safety and efficacy have not been established and thereby is subject to recall. Furthermore, the FDA has determined the product to be misbranded with a misleading label similar in appearance to the FDA-approved drug product Adrenalin® (epinephrine ***injection***) (1 mg/mL) 30 mL vial, also produced by Endo.

Both products are distributed to hospitals and healthcare systems for use by health care professionals and are similarly labeled making it difficult to distinguish between the *non-sterile topical* and *sterile injectable* product which can lead to potential administration errors. This recall does not include the approved Adrenalin (epinephrine ***injection***) (1 mg/mL) 30 mL vial.

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 on the following page.

Adrenalin Chloride Solution (epinephrine ***nasal solution***) is a vasoconstrictor for topical application into the nose. The recalled product has language “Nasal Solution USP” and “For Topical Application” on the package.

What this means to you:
Intravenous (IV) administration of the unapproved *non-sterile topical* Adrenalin Chloride Solution (epinephrine ***nasal solution***) instead of the approved *sterile* Adrenalin (epinephrine ***injection***) could lead to serious health outcomes such as an infection caused by lack of product sterility. Furthermore, it is likely that IV administration of the ***nasal*** product will result in patients receiving the ***wrong dose*** of epinephrine, and in emergency situations (such as serious allergic reactions, low blood pressure, or cardiac arrest), if these events are not treated with the correct dose of epinephrine, patients may be at risk for death.

Questions regarding this recall can be directed to Inmar at 1-877-560-8453 Monday through Friday between the hours of 9 a.m. and 5 p.m. EST or by email at rxrecalls@inmar.com. For medical or technical product information or to report a product complaint or adverse event please call 1-800-828-9393.

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 (US) 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/endo-usa-inc-issues-voluntary-nationwide-recall-adrenalinr-chloride-solution-epinephrine-nasal

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.