Dec. 20, 2024

Endo issues voluntary nationwide recall of Adrenalin chloride solution (epinephrine nasal solution) due to potential for administration errors

At Prime Therapeutics Management, we want to help you receive the best possible care. Visit **PrimeTherapeutics.com/DrugRecalls** to review the latest FDA drug recalls.

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 predates the 1938 Federal Food, Drug & Cosmetic Act and was never submitted for Food and Drug Administration (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 health care systems for use by health care professionals and are similarly labeled, making it difficult to distinguish between the nonsterile 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.

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 nonsterile 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 **877.560.8453**, Monday–Friday, 9 a.m.–5 p.m. Eastern Standard Time (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 **800.828.9393**.

All brand names are property of their respective owners.
FOR_176350 07/25 © 2025 Prime Therapeutics Management LLC, A Prime Therapeutics LLC Company