COMPANY ANNOUNCEMENT

Sagent Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Phenylephrine Hydrochloride Injection, USP, 10 mg/mL Due to Potential Lack of Sterility Assurance

Summary

Company Announcement Date:

March 11, 2021

FDA Publish Date:

March 11, 2021

Product Type:

Drugs

Reason for Announcement:

Lack of sterility assurance

Company Name:

Sagent Pharmaceuticals, Inc.

Brand Name:

Sagent

Product Description:

Phenylephrine Hydrochloride Injection

Company Announcement

Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of three lots of Phenylephrine Hydrochloride Injection, USP (10 mg/mL). This product was manufactured by Indoco Remedies Ltd. and distributed by Sagent Pharmaceuticals, Inc. Sagent has initiated this voluntary recall of Phenylephrine Hydrochloride Injection, USP to the user level as the result of a customer complaint due to potentially loose crimped vial overseals. A non-integral crimped vial overseal may result in a non-sterile product.

Intravenous administration of a product intended to be sterile that is not sterile could result in serious systemic infections which may be life-threatening. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. To date, Sagent has not received reports of any adverse events associated with this issue.

Phenylephrine Hydrochloride Injection, USP is an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important low blood pressure resulting primarily from the dilation of blood vessels, which decreases blood pressure in the setting of anesthesia.

The product is supplied in 3 mL glass tubular vials. The lot numbers being recalled were distributed to hospitals, wholesalers and distributors nationwide in the USA from 11/17/2020 – 03/08/2021.

Product	Lot Number	Expiration Date	NDC Number	Distribution Dates
Phenylephrine Hydrochloride Injection, USP	PHT8IB2 PHT9IB2 PHT1JB2	08/2022 08/2022 09/2022	25021-315-01	November 17, 2020 – March 8, 2021

Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lots listed above. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. Consumers/distributors/retailers that have product which is being recalled should stop using product and return the recalled product. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.com (http://www.Sagentpharma.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Customers or consumers with any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F, 8am-7pm CST. Healthcare workers who have medical questions about Phenylephrine Hydrochloride Injection, USP, may contact Medical Affairs (866-625-1618, Option 3) M-F, 8am-5pm CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)

- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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.

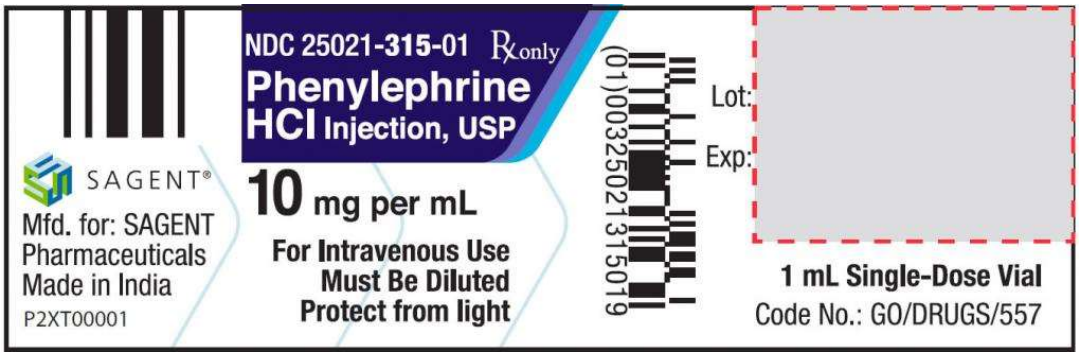
Company Contact Information

Consumers:

Customer Call Center

(866) 625-1618

Product Photos



More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)