DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Sandoz Issues Nationwide Recall of 1 Lot of Enoxaparin Sodium Injection 40 mg/0.4 mL Due to Temperature Excursion During Shipping

December 2, 2021

Sandoz Inc. ("Sandoz") is initiating a recall of one lot (SAB06761A, Exp 04/2023) of Enoxaparin Sodium Injection, USP 40 mg/0.4 mL Single-Dose Syringes to the consumer level. A portion of lot SAB06761A experienced a temperature excursion during shipment. Enoxaparin Sodium for Injection Lot SAB06761A was shipped to customers in the months of September and October 2021.

The exposure to higher temperatures may have significantly impacted the recalled product's (lot SAB06761A) effectiveness and thus there may be reasonable probability of risk for patients with health conditions that the product is intended to treat. Such patients could be at risk for blood clots blocking blood vessels, an artery, or traveling to other tissues or organs causing pain, swelling, stroke, clots to the lung or death as a result of the underlying condition. To date, Sandoz has not received any reports of adverse events or injuries related to this recall.

The product is used for prevention of deep vein thrombosis (DVT) a condition that occurs when a blood clot forms in a deep vein, usually in the legs that can occur after surgeries or in patients with restricted mobility during illness; or prevention of complications associated with heart attacks. The product is packaged in cartons containing ten 0.4 mL syringes, NDC 0781-3246-64. Enoxaparin Sodium Injection was distributed Nationwide in the USA to wholesalers and retailers.

Product Name	NDC Number	Lot Number	Expiration Date	Date of Manufacture
Enoxaparin Sodium Injection, USP 40 mg/0.4 mL	0781-3246-64	SAB06761A	04/2023	05/26/2021

Please note: this recall is specific to only one batch (SAB06761A) of Enoxaparin Sodium Injection, USP 40 mg/0.4 mL and does not apply to any other strengths of Sandoz Enoxaparin Sodium Injection, USP or to other lots of the 40 mg/0.4 mL SKU.

Any product returned that is not associated with this recall will be destroyed and no credit issued.

Sandoz has already notified its wholesalers and retailers by mail and is arranging for return of all recalled product.

Consumers who have Enoxaparin Sodium Injection, USP 40 mg/0.4 mL (NDC 0781-3246-64 and Lot number SAB06761A) which is being recalled, should stop taking the recalled product and immediately consult with their physician to attain another prescription. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Retailers and consumers should contact Sedgwick directly by phone at 844-265-7389 to return the recalled product. Representatives are available Monday – Friday, 8:00 am – 5:00 pm ET.

In case of any adverse reactions, please call Sandoz at (800) 525-8747 or email qa.drugsafety@sandoz.com. Customer service agents are available Monday – Friday from 8:30 am to 5:00 pm ET. Adverse events can also be reported to FDA online at www.fda.gov/medwatch/report.htm.

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 U.S. Food and Drug Administration.

*Enoxaparin sodium injection is a product of Sandoz, Inc.

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-nationwide-recall-one-lot-enoxaparin-sodium-injection-usp-40mg04-ml-due