RXADVANCE
136 Turnpike Road
Southborough, MA 01772

Enoxaparin Sodium Injection Recall Alert

Date of Notice: 12/01/2021

Brief Description of Recall Alert

Princeton, NJ, Sandoz Inc. ("Sandoz") is initiating a recall of one lot of enoxaparin sodium Injection, USP 40 mg/0.4 mL single-dose syringes. A portion of the lot experienced a temperature deviation during shipment, which was shipped in the months of September and October 2021.

The exposure to higher temperatures may have significantly impacted the recalled product's 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 because of the underlying condition.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
enoxaparin sodium injection, USP 40 mg/0.4 mL	00781-3246-64	SAB06761A	04/2023

Prescriber Information

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. To date, Sandoz has not received any reports of adverse events or injuries related to this recall.

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

Pharmacists should contact Sedgwick directly by phone at 844-265-7389 or by email at sandoz4623@sedgwick.com to request a recall packet. Representatives are available Monday – Friday, 8:00 am – 5:00 pm ET.

Member Information

Members who have enoxaparin sodium injection, USP 40 mg/0.4 mL which is being recalled, should stop taking the recalled product, immediately consult with their doctor to attain another prescription, and return the product where originally purchased. Members should contact their doctor or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

RxAdvance Response

Members should stop taking the affected lot and call their doctors to attain another prescription.