COMPANY ANNOUNCEMENT

Sandoz, Inc. Issues Nationwide Recall of One Lot of Enoxaparin Sodium Injection, USP 40mg/0.4 mL Due to Temperature Excursion During Shipping

Summary

Company Announcement Date:

December 01, 2021

FDA Publish Date:

December 02, 2021

Product Type:

Drugs

Reason for Announcement:

Exposure to high temperatures may have impacted product effectiveness.

Company Name:

Sandoz, Inc.

Brand Name:

Sandoz

Product Description:

Enoxaparin Sodium Injection

Company Announcement

FOR IMMEDIATE RELEASE – December 1, 2021 – Princeton, NJ, 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.

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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	00781-3246-64	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 00781-3246-64 and Lot number SAB06761A) which is being recalled, should stop taking the recalled product, immediately consult with their physician to attain another prescription, and return the product where originally purchased. 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.

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.

In case of any adverse reactions, please call Sandoz at (800) 525-8747 or email qa.drugsafety@sandoz.com (mailto: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

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reported to FDA online at www.fda.gov/medwatch/report.htm (http://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 (/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.

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

INDICATION AND IMPORTANT SAFETY INFORMATION

Please see full Prescribing Information (https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bbebb81f-5137-4097-b91f-7ee87bd12bcf) **for additional safety information.**

Disclaimer

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potentially,” “can,” “will,” “may,” “could,” “initiating,” or similar terms, or by express or implied discussions regarding the potential outcome of the nationwide recall of Enoxaparin Sodium Injection 40MG Lot #SAB06761A, or regarding potential future revenues from such product. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee as to the outcome of the nationwide recall of Enoxaparin Sodium Injection 40MG Lot #SAB06761A. In particular, our expectations regarding such product could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional generic or biosimilar versions of such product; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement

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pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical need. Our ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2020 sales of USD 9.6 billion.

Sandoz on social media

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