RXADVANCE
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Enoxaparin Sodium Injection, USP Recall Alert

Date of Notice: 02/02/2021

Brief Description of Recall Alert

Apotex Corp is voluntarily recalling two (2) batches of enoxaparin sodium injection, USP due to a packaging error resulting in some syringe barrels containing 150 mg/mL markings (corresponding to 120 mg/0.8mL strength) instead of 100 mg/mL markings (corresponding to 100 mg/mL strength) on the syringe barrel and vice versa. The packaging error was discovered during a customer complaint investigation. The affected product is manufactured by Gland Pharma Limited, Hyderabad, India.

Enoxaparin sodium injection is indicated for the prevention of deep vein thrombosis (DVT) and/or pulmonary embolism (PE), treatment of acute DVT, prevention of ischemic complications of unstable angina and non-Q-wave myocardial infarction (heart attack), and treatment of acute ST-segment elevation myocardial infarction (heart attack).

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
enoxaparin sodium injection, USP 100 mg/mL	60505-0795-1	CS008	04/2022
enoxaparin sodium injection, USP 120 mg/0.8 mL	60505-0796-0	CT003	05/2022

Prescriber Information

The two (2) affected batches of enoxaparin sodium injection, USP were distributed by Apotex nationwide in the USA to wholesalers and warehousing chains. Apotex Corp. is currently notifying its affected direct account wholesalers and warehousing chains, via mail (FedEx Standard Overnight) by mailing a recall notification letter and is arranging for return of all recalled product. To date, Apotex has not received any reports of adverse events related to use of these two batches.

Health Hazard Assessment: Incorrect syringe barrel marking could lead to miscalculation and inaccurate patient dose administration. In one recalled batch (batch CS008, strength 100 mg/mL), if a patient used a 150 mg/mL concentration packaged in a barrel corresponding to a 100 mg/mL concentration, the patient could receive 3.75 mg of enoxaparin, instead of 3 mg of enoxaparin. In the other recalled batch (batch CT003, strength 120 mg/0.8mL), if a patient used a 100 mg/mL concentration packaged in a barrel corresponding to a 150 mg/mL concentration, the patient would receive 2 mg of enoxaparin rather than 2.5 mg of enoxaparin. Accidental overdosage following administration of enoxaparin sodium injection may lead to bleeding complications. Alternatively, if the dose administered is less than prescribed, the patient may be subject to developing some blood clotting conditions.

Wholesalers, distributors, and retailers should return the recalled product to the place of purchase. Anyone with an existing inventory of the product should quarantine the recalled batches immediately. Customers who purchased the impacted product directly from Apotex can call Inmar Rx Solutions at 1-855-667-8717 (9:00am – 5:00-pm, EST Monday thru Friday), to arrange for their return.

Customers with the affected units of enoxaparin sodium injection, USP should contact Inmar Rx Solutions ("Inmar") at 1-855-667-8717, to receive a recall/return packet including the recall stock response form, or you may obtain this form from clsnetlink.com

Adverse reactions or quality problems experienced with the use of this drug 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

Member Information

Patients who have received either of the two (2) impacted batches of enoxaparin sodium injection, USP or have questions regarding this recall should contact their pharmacy. Patients should not interrupt their therapy. Patients should immediately contact their health care provider for medical advice and should return the impacted product to their pharmacy.

Members with questions regarding this recall can contact Apotex Corp. by phone at 1-800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday) or email address UScustomerservice@Apotex.com. 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

RxAdvance recommends that you speak to your doctor before you stop taking the drug. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.