Apotex Issues Voluntary Nationwide Recall of Enoxaparin Sodium Injection, USP Due to Mislabeling of Syringe Barrel Measurement Markings

FDA Publish Date: 2/3/2021

Apotex is voluntarily recalling 2 batches of Enoxaparin Sodium Injection, USP to the consumer level due to a packaging error resulting in some syringes barrels containing 150 mg/mL markings (corresponding to the 120 mg/ 0.8 mL strength) instead of 100 mg/mL markings (corresponding to the 100 mg/mL strength) on the syringe barrel and vice versa. The packaging error was discovered during a customer complaint investigation. To date, Apotex has not received any reports of adverse events related to use of these two batches. The affected product is manufactured by Gland Pharma.

Health Hazard Assessment: Incorrect syringe barrel marking could lead to miscalculation and inaccurate dose administration. In one recalled batch (batch CS008, strength 100 mg/mL), if a consumer 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 another recalled batch (batch CT003, strength 120 mg/0.8 mL), if a consumer 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 could result in bleeding complications. Alternatively, if the dose administered is less than prescribed, the patient may experience blood clotting events.

Enoxaparin sodium injection is indicated for the prophylaxis of deep vein thrombosis (DVT) which may lead to pulmonary embolism (PE), treatment of acute DVT, prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction (MI) when concurrently administered with aspirin, and treatment of acute ST-segment elevation MI.

The 2 impacted batches of enoxaparin sodium injection, USP were distributed by Apotex nationwide in the United States (US) to wholesalers and warehousing chains. Apotex 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.

The impacted enoxaparin sodium injection can be identified by NDC numbers found on the carton and label of the product. The table on the following page also provides additional details including the 2 recalled batch numbers.

Product	Batch #	Strength	Syringe Barrel Measurement Markings	Package Size	NDC Number on Carton	NDC Number on label	UPC Code on Carton	UPC Code on label
Enoxaparin Sodium Injection, USP	CS008	100 mg/mL	100 mg/mL	10 x 1 mL single dose syringes	60505-0795-4	60505-0795-1	360505079544	(01)10360505079510
	CT003	120 mg/0.8 mL	150 mg/mL	10 x 0.8 mL single dose syringes	60505-0796-4	60505-0796-0	360505079643	(01)10360505079602

Patients who have received either of the 2 recalled batches of enoxaparin sodium injection or have questions regarding this recall should contact their pharmacy. The FDA recommends individuals *not* interrupt their therapy, immediately contact their healthcare provider for medical advice, and return the impacted product to Inmar Rx Solutions by contacting the numbers provided in this press release.

Consumers with the affected units of enoxaparin sodium injection, please 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.

Consumers with questions regarding this recall can contact Apotex by phone at 1-800-706-5575 (8:30 am – 5 pm, EST Monday to Friday) or via email at UScustomerservice@Apotex.com. **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.

Wholesalers, distributors, and retailers should return the recalled product to the place of purchase. Anyone with existing inventory 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 (9:00 am – 5:00 pm, EST Monday to Friday), to arrange for their return.**

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 US Food and Drug Administration.

Link to FDA recall notification: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-enoxaparin-sodium-injection-usp-due-mislabeling

Company Contact Information

Consumers:

Apotex Corp.
1-800-706-5575
UScustomerservice@Apotex.com

Media:

Jordan Berman
1-416-749-9026
jberman@apotex.com

Product Photos

Click here for product photos.