DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

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

February 2, 2021

Apotex Corp is voluntarily recalling two (2) batches of Enoxaparin Sodium Injection, USP to consumer level due to a packaging error resulting in some syringes 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. 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 Limited, Hyderabad, India.

Health Hazard Assessment: Incorrect syringe barrel marking could lead to miscalculation and inaccurate dose administration to patients. In one recalled batch (batch CT003, strength 120 mg/0.8mL), if a consumer used a syringe with an incorrect barrel having markings associated with the l00 mg/mL barrel, patients could receive 3.75 mg of Enoxaparin, instead of 3 mg of Enoxaparin. In another recalled batch (batch CS008, strength 100 mg/mL), if a consumer used a syringe with an incorrect barrel having markings associated with the 150 mg/mL barrel, patients 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. Alternative, if the dose administered is less than prescribed, the patient may be subject to developing some blood clotting conditions.

Enoxaparin Sodium injection is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), Treatment of Acute Deep Vein Thrombosis, prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction, when concurrently administered with aspirin and Treatment of Acute ST-Segment Elevation Myocardial Infarction.

The affected Enoxaparin Sodium Injection, USP can be identified by NDC numbers stated on carton and label of the product.

Product	Batch #	Strength	Syringe Barrel Measurement Markings	Pack Size	NDC NumberOn 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 1mL Single Dose Syringes	60505-0795-4	60505-0795-1	360505079544	(01)10360505079510
	CT003	120 mg/0.8mL	150 mg/ mL	10 x 0.8 mL Single Dose Syringes	60505-0796-4	60505-0796-0	360505079643	(01)10360505079602

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.

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. Individuals should not interrupt their therapy, should immediately contact their health care provider for medical advice and should return the impacted product to Inmar Rx Solutions by contacting at the numbers provided in this press release.

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.**

Consumers with the affected units of Enoxaparin Sodium Injection, USP, 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 https://clsnetlink.com

Consumers 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. **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.

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: www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda
- Regular Mail or Fax: Download form www.fda.gov/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.

Company Contact Information

Consumers:

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1-800-706-5575
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Media:

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