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

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Apotex has posted a lot recall of Enoxaparin Sodium Injection.

About this Recall:
Apotex is voluntarily recalling 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 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.

What this means to you:
Incorrect syringe barrel marking could result in inaccurate dose administration. In recalled batch CS008 (strength 100 mg/mL), patients could receive 3.75 mg of enoxaparin, instead of 3 mg of enoxaparin. In the other recalled batch (batch CT003, strength 120 mg/0.8 mL), patients could receive 2 mg of enoxaparin rather than 2.5 mg of enoxaparin. Accidentally taking too much drug may result in bleeding complications. Alternatively, if the dose administered is less than prescribed, blood clotting events could occur.

Enoxaparin sodium injection is used for the treatment of acute deep vein thrombosis (DVT), prevention of DVT which can lead to pulmonary embolism (PE), as well as for the prevention and treatment of certain cardiac events.

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

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

Consumers with the impacted 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 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.

For more information regarding this FDA Recall Notification, please refer to the FDA website:

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

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.