February 4, 2021 **COM-2021-008**

RECALL NOTIFICATION

FDA PUBLICATION DATE: February 3, 2021

DRUG NAME: Enoxaparin Sodium Injection, USP

COMPANY: Apotex Corp

REASON: Packaging error resulting in incorrect dosage listed

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug recalls. It is for this reason that we are notifying you that on February 3, 2021 the US Food and Drug Administration (FDA) published a voluntary drug recall for two batches of Enoxaparin Sodium Injection, USP to consumer level due to a packaging error resulting in 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.

Affected products:

See next page.

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Product	Batch Number	Strength	Syringe Barrel Measurement Markings	Pack 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 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

Pharmacy required action(s):

- Identify if the product is on inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication.
- Advise patients to contact their physician if they have experienced any problems that may be related to taking or using this product.
- Advise patients to continue taking their medication, and to contact their physician for advice regarding an alternative treatment, and if they have experienced any problems that may be related to taking or using the recalled drug product.
- Return the recalled product to the place of purchase.

Contact information:

- For further details, contact Apotex Corp. by phone at 1-800-706-5575 (8:30am – 5:00pm, EST Monday thru Friday) or email address UScustomerservice@Apotex.com.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- Apotex Corp. Issues Voluntary Nationwide Recall of Enoxaparin Sodium Injection, USP Due to Mislabeling of Syringe Barrel Measurement Markings. February 3,2021, from: file:///C:/Users/drodriguez/Downloads/COM-2021-005-Drug%20Recall%20Ketorolac%20Inj%20-%20Fresenius-Jan-2021-Final.pdf

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