## Apotmex – Recall of enoxaparin injection

- On February 2, 2021, Apotex announced a voluntary, consumer level recall of two lots of enoxaparin injection 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 recalled lots are listed below:

| Product Description | NDC# | Lot# (Expiration Date) |
|---|---|---|
| Enoxaparin sodium injection, 100 mg/mL, 10 x 1 mL single dose syringes | 60505-0795-4 (# on carton) | CS008 (4/2022) |
| | 60505-0795-1 (# on syringe) | |
| Enoxaparin sodium injection, 120 mg/0.8 mL, 10 x 0.8 mL single dose syringes | 60505-0796-4 (# on carton) | CT003 (5/2022) |

- Enoxaparin is indicated for the prophylaxis of deep vein thrombosis, treatment of acute deep vein thrombosis, prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction (MI), and for the treatment of acute ST-segment elevation MI.

- Incorrect syringe barrel marking could lead to miscalculation and inaccurate dose administration to patients.

    - In lot 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, patients could receive 3.75 mg of enoxaparin, instead of 3 mg of enoxaparin.
    - In lot CT003 (strength 120 mg/0.8mL), if a consumer used a 100 mg/mL concentration packaged in a barrel corresponding to a 150 mg/mL concentration, patients would receive 2 mg of enoxaparin rather than 2.5 mg of enoxaparin.

- Accidental overdosage or underdosage following administration of enoxaparin injection may lead to bleeding complications or blood clotting conditions, respectively.

- To date, Apotex has not received reports of any adverse events or identifiable safety concerns attributed to use of the recalled lots.

- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to the recalled enoxaparin injection.

- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.

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- Contact Apotex by phone at **1-800-706-5575** or by email at **UScustomerservice@Apotex.com** for more information about this recall. Contact Inmar (appointed company for Apotex) at **1-855-667-8717** for return and refund information.