Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

D R U G   A L E R T

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level

Date: 04 August 2020	EL (20)A/37	Our Ref: MDR 229-07/20

Dear Healthcare Professional,

Pharmaram Ltd

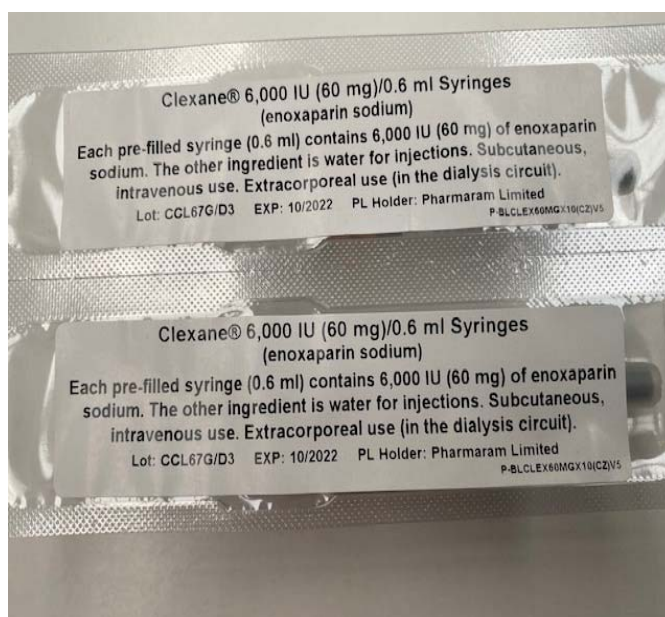## Clexane 4,000 IU (40mg) /0.4ml Syringes   PLPI 33652/0067

Batch Number	Expiry Date	Pack Size	First Distributed
CCL67G/D3	31/10/2022	10 syringes per pack	16/07/2020

Active Pharmaceutical Ingredient: Enoxaparin sodium

Brief description of the problem

Pharmaram Ltd has informed us that the above batch of Clexane 4,000IU (40mg)/0.4ml syringes has an error on the labelling affixed to the plastic blister packaging encasing the syringe. The label incorrectly states "Clexane 6,000IU (60mg)/0.6ml Syringes", when it should have stated "Clexane 4,000IU (40mg)/0.4ml Syringes". The outer carton states the correct strength; the batch number and expiry dates are also correct and match the details on the labelling.

Advice for healthcare professionals

- Stop supplying the above products immediately and remove from the shelves within your pharmacy/store. Quarantine all remaining stock and return these to your supplier using your supplier's approved process.

- Patients who have been supplied this batch of Clexane 4,000IU (40mg)/0.4ml Syringes should be informed that the error is only with the labelling on the plastic blister packaging encasing the syringe.

Further Information

For stock control queries please contact:

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For any medical information enquires please contact:
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Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

NHS England and NHS Improvement Regional Offices are asked to forward this alert to community pharmacy contractors.

Yours faithfully

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