Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL, EL(25)A/27

Action within 48 hours

Issued 12 June 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Quadrant Pharmaceuticals Limited / Maxearn Limited

MEDICINE DETAILS

Inhixa 12,000IU (120mg)/0.8mL solution for injection

PLPI 20774/2461

Active Ingredient: enoxaparin sodium

SNOMED code: N/A

GTIN: 05060537819778

AFFECTED LOT BATCH NUMBERS

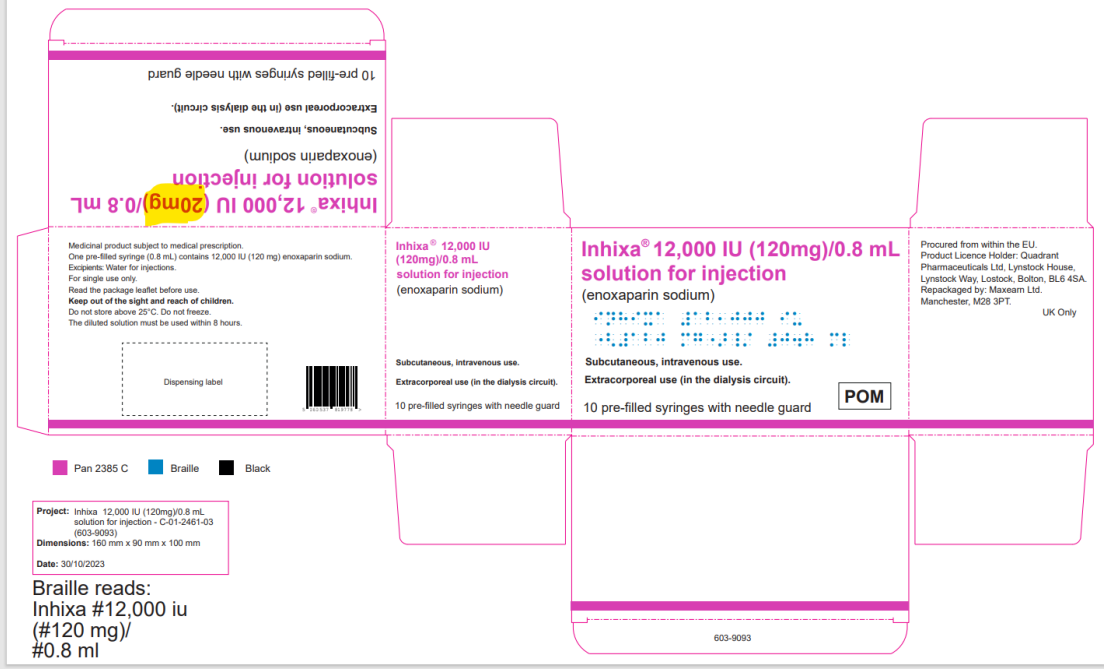
Batch No.	Expiry Date	Pack Size	First Distributed
0191Y / AG07093D	31/05/2026	**10**	16/04/2025
9982X / AG11871C	31/03/2026	**10**	16/04/2025

Background

Maxearn Limited have informed the MHRA that the carton used to package two imported batches of Inhixa have been released to the market with a typographical error on one side of the carton. The incorrect strength of the product is written on one side of the carton which states “12,000 IU (20mg)/0.8 ml solution for injection” instead of the correct strength “12,000 IU (120mg)/0.8 ml solution for injection”. The remainder of the packaging, including three other sides of the carton, the Patient Information Leaflet (PIL) and the labels on the individual pre-filled syringes all contain the correct strength details.

The error only impacts the parallel imported product repackaged by Maxearn, packs from other sources are not affected and should continue to be dispensed.

The incorrect strength is highlighted in the image of the carton below.



Advice for Healthcare Professionals:

Stop supplying the above batch immediately. Quarantine all stock and return it to your supplier using your supplier's approved process.

Maxearn have informed MHRA that approximately 14 defective packs (each containing 10 prefilled syringes) have been released to pharmacies. All other units from these batches have been held before onward distribution. Maxearn will arrange for customers to be contacted, including pharmacies, that have received the defective packs.

Pharmacists who have been supplied this batch and suspect they have dispensed the medicine to patients should contact the patient immediately to make them aware of this error. Please see 'advice for patients' section below.

Advice for Patients:

Patients who have been prescribed Inhixa 2,000 IU (20mg)/0.2 mL should check the batch number of their pre-filled syringes, (printed on the foil of the individual prefilled syringe label or on the carton). Patients who have received batches 0191Y / AG07093D or 9982X / AG11871C, should contact their pharmacist or GP immediately.

Patients who have been prescribed 12,000 IU (120mg)/0.8 ml should verify the strength of the medicine by checking the information on the other sides of the carton, PIL

included and inner labels on the actual syringe. Continue to take the medicine as prescribed by your doctor.

Do not stop taking your medicine without consulting your healthcare provider. Patients who are concerned about the strength of the medication they have received should check it with their dispensing pharmacy.

Patients who are concerned they may have taken an incorrect dose of the medication than what should have been prescribed should seek medical attention.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For all medical information enquiries and information on this product, please email maxearnqa@maxearn.co.uk or telephone 01204 471 269.

For stock control enquiries please email maxearnqa@maxearn.co.uk or telephone 01204 471 269.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU

Telephone +44 (0)20 3080 6574

DMRC@mhra.gov.uk