MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/04

Caution In Use

Issued 28 January 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Viatris Products Ltd

MEDICINE DETAILS

Arixtra 1.5 mg/0.3 ml solution for injection, pre-filled syringe
PLGB: **46302/0230**
Active Ingredient: **fondaparinux sodium**
SNOMED code: **13565111000001103**
GTIN: **05016695926704**

MEDICINE DETAILS

Arixtra 2.5 mg/0.5 ml solution for injection, pre-filled syringe
PLGB: **46302/0231**
Active Ingredient: **fondaparinux sodium**
SNOMED code: **4332811000001106**
GTIN: **05016695926759**

MEDICINE DETAILS

Arixtra 5 mg/0.4 ml solution for injection, pre-filled syringe
PLGB: **46302/0232**
Active Ingredient: **fondaparinux sodium**
SNOMED code: **9205511000001101**
GTIN: **05016695926698**

MEDICINE DETAILS

Arixtra 7.5 mg/0.6 ml solution for injection, pre-filled syringe

PLGB: **46302/0233**

Active Ingredient: **fondaparinux sodium**

SNOMED code: **9205811000001103**

GTIN: **05016695926674**

MEDICINE DETAILS

Arixtra 10 mg/0.8 ml solution for injection, pre-filled syringe

PLGB: **46302/0229**

Active Ingredient: **fondaparinux sodium**

SNOMED code: **9206111000001104**

GTIN: **05016695926681**

AFFECTED LOT BATCH NUMBERS

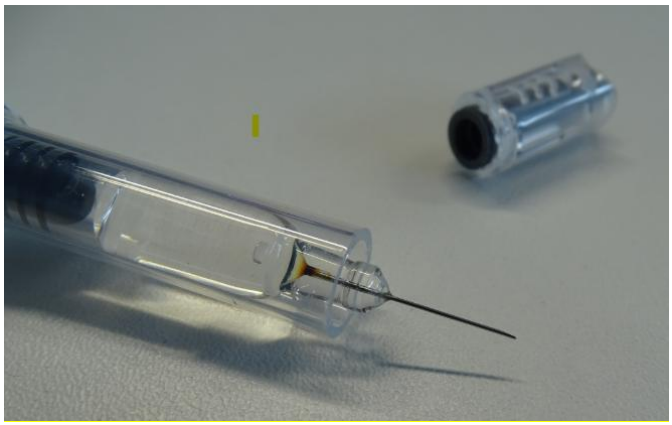
All batches of Arixtra solution for injection, pre-filled syringe within expiry date are affected

Background

Viatris has received reports of brown discolouration and blockage in the needle of pre-filled syringes of Arixtra. This quality defect is related to oxidation of the syringe needle.

The defect occurrence is estimated to be very rare. As Arixtra is considered critical to the continued supply of this medication, it will remain available for prescribing and is not being recalled from the market.

Figure 1: Example of syringe with discolouration at the base of the needle



Advice for Healthcare Professionals:

Follow the below handling precautions before dispensing or administering Arixtra:

Carefully inspect all Arixtra pre-filled syringes for discolouration at the needle base; if the needle base in the pre-filled syringe is discoloured (as illustrated in Figure 1), do not dispense or administer Arixtra and return it to your supplier using your supplier's approved process.

Inform patients and caregivers of this quality defect and advise them on the handling precautions.

Advice for Healthcare Professionals to Provide to Patients:

Carefully inspect all Arixtra pre-filled syringes for discolouration at the needle base. If the needle base in the pre-filled syringe is discoloured (as illustrated in Figure 1), do not administer Arixtra and return it to the pharmacy.

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

Additional information:

For medical information enquiries please telephone Viatris UK Healthcare Limited Medical Information on +44 (0)1707 853 000 (select option 1) or email info.uk@viatris.com.

For stock control enquiries please contact telephone Customer Services on +44 (0)1707 853 000 (select option 2).

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