Arixtra (fondaparinux sodium): Serious quality defect related to the needle in pre-filled syringe

6 February 2026

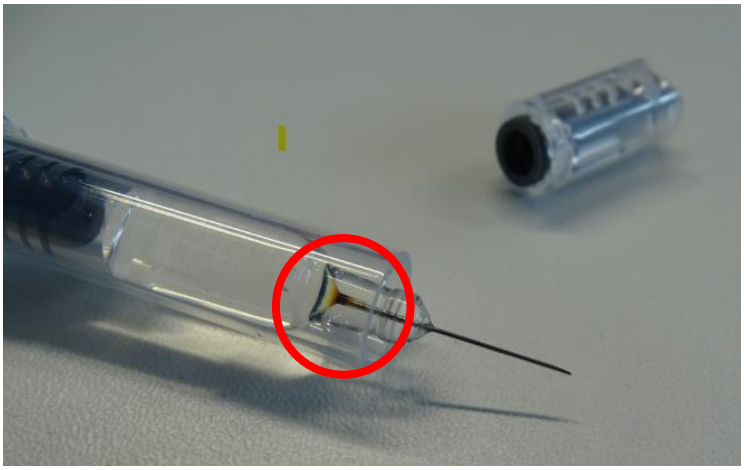
Dear Healthcare professional,

Viatris Healthcare Limited, in agreement with the European Medicines Agency and the <National Competent Authority > would like to inform you of the following:

Summary

- **Viatris has received reports of brown discoloration and blockage in the needle of pre-filled syringes of Arixtra. This quality defect is related to the presence of an extraneous iron particle inside the needle which has oxidized.**
- **While the defect is estimated to be very rare, it can randomly occur among the batches currently distributed on the market and can potentially impact all presentations of Arixtra.**
- **Follow the below handling precautions before dispensing or administering Arixtra :**
    - **Carefully inspect all Arixtra pre-filled syringes for discoloration at the needle base;**
    - **If the needle base in the pre-filled syringe is discolored (as illustrated in Figure 1), do not dispense or administer Arixtra; instead, return it to the wholesaler and/or Viatris for a replacement.**
- **Inform patients and caregivers of this quality defect and advise them on the handling precautions, including the requirement to return any units in which they observe the quality defect.**

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



Background information

Depending on the strength, Arixtra is indicated for:

- Prevention of Venous Thromboembolic Events (VTE) in patients undergoing major orthopaedic surgery of the lower limbs such as:
  - hip fracture, including extended prophylaxis
  - knee replacement surgery
  - hip replacement surgery.
- Prevention of Venous Thromboembolic Events (VTE) in patients undergoing abdominal surgery who are at risk of thromboembolic complications.
- Prevention of Venous Thromboembolic Events (VTE) in medical patients who are at risk of thromboembolic complications due to restricted mobility during acute illness.
- Treatment of acute Deep Vein Thrombosis (DVT).
- Treatment of acute Pulmonary Embolism (PE).
- Treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) acute coronary syndrome for the prevention of death, myocardial infarction and refractory ischaemia. Fondaparinux has been shown to reduce all cause mortality in patients with UA/NSTEMI.
- Treatment of ST segment elevation myocardial infarction (STEMI) acute coronary syndrome for the prevention of death and myocardial re-infarction in patients who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy. Fondaparinux has been shown to reduce all cause mortality in patients with STEMI.
- Treatment of acute symptomatic superficial-vein thrombosis of the lower limbs without concomitant Deep-Vein Thrombosis (DVT).

Of note, locally approved indications may differ.

Arixtra is authorised in the EU/EEA in the following presentations:

- Arixtra 1.5 mg/0.3 ml solution for injection, pre-filled syringe;
- Arixtra 2.5 mg/0.5 ml solution for injection, pre-filled syringe;
- Arixtra 5 mg/0.4 ml solution for injection, pre-filled syringe;
- Arixtra 7.5 mg/0.6 ml solution for injection, pre-filled syringe;
- Arixtra 10 mg/0.8 ml solution for injection, pre-filled syringe.

To date, the ongoing manufacturing investigation shows that all batches have been manufactured, packed and tested according to Marketing Authorization Dossier and conform to the registered specifications. The investigation is in progress to identify the root cause and implement appropriate corrective/preventive actions.

The potential risks of utilizing a pre-filled syringe which is discolored include lack of efficacy due to blockage of the needle as well as adverse events if impacted injections are administered. These events may include hypersensitivity reactions, injection site complications (including needle breakage), thromboembolic effects, and systemic infections.

Call for reporting

Healthcare professionals are asked to report any product defect in accordance with the national spontaneous reporting system and include batch/Lot number if available. < include the details (e.g. name, postal address, phone number, website address) on how to access the national spontaneous reporting system>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>