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

05 Feb 2026

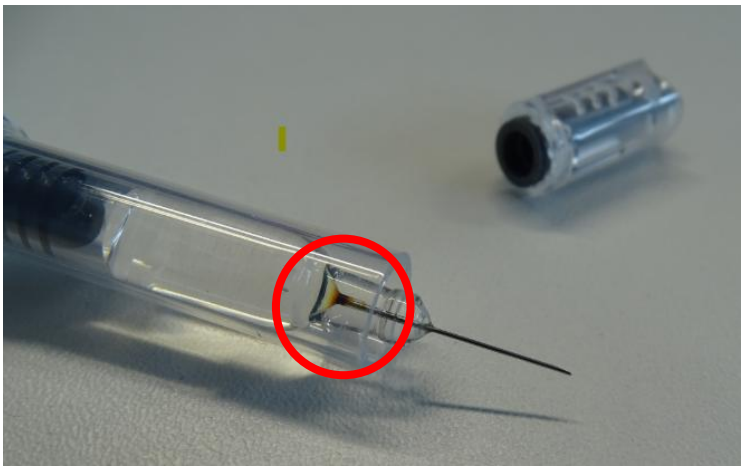
Dear Healthcare professional,

Viatris Healthcare Limited, in agreement with the European Medicines Agency the Malta Medicines 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.

Approved indications, as per the approved SmPC for the strengths marketed in Malta:

- For Arixtra 2.5 mg/0.5 ml solution for injection, pre-filled syringe:

Prevention of Venous Thromboembolic Events (VTE) in adults undergoing major orthopaedic surgery of the lower limbs such as hip fracture, major knee surgery or hip replacement surgery.

Prevention of Venous Thromboembolic Events (VTE) in adults undergoing abdominal surgery who are judged to be at high risk of thromboembolic complications, such as patients undergoing abdominal cancer surgery.

Prevention of Venous Thromboembolic Events (VTE) in adult medical patients who are judged to be at high risk for VTE and who are immobilised due to acute illness such as cardiac insufficiency and/or acute respiratory disorders, and/or acute infectious or inflammatory disease.

Treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) in adults for whom urgent (< 120 mins) invasive management (PCI) is not indicated.

Treatment of ST segment elevation myocardial infarction (STEMI) in adults who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy.

Treatment of adults with acute symptomatic spontaneous superficial-vein thrombosis of the lower limbs without concomitant deep-vein thrombosis.

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

Treatment of adults with acute Deep Vein Thrombosis (DVT) and treatment of acute Pulmonary Embolism (PE), except in haemodynamically unstable patients or patients who require thrombolysis or pulmonary embolectomy.

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 on https://medicinesauthority.gov.mt/complaints. Complaints may be sent through the online form or by e-mail on: info.medicinesauthority@gov.mt or in writing at Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000.

You can report side effects directly using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;

Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000

E-mail: postlicensing.medicinesauthority@gov.mt

Company contact point

Alternatively, they may be reported by contacting Viatris's local representative V.J. Salomone Pharma Ltd. at +35699644126, and/or regvjsp@vjsalomone.com