



EMA/449395/2017 Rev.2

Update of 20 March 2018:

The shortage affecting Arixtra has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

13 July 2017

Shortage of Arixtra (fondaparinux sodium) Pre-filled syringes	
Indication	Arixtra is used to prevent and treat blood clots in the veins, and to treat patients with pulmonary embolism (clot in a blood vessel in the lungs), unstable angina (a severe type of chest pain) or who are having a heart attack.
Reason for shortage	A minor defect affecting the needle guard of some Arixtra syringes had led to quarantine of several batches and interrupted production, causing a supply shortage of some strengths (1.5, 2.5, 5.0 and 7.5 mg pre-filled syringes).
Member States affected¹	The EU Member States that are currently impacted by the shortage are: Austria, Czech Republic, Cyprus, Denmark, Finland, France, Germany, Greece, Italy, Netherlands, Poland, Slovak Republic, Slovenia, Sweden and the United Kingdom as well as Iceland and Norway.
Information for healthcare professionals	<ul style="list-style-type: none">• Because of a minor defect affecting the needle guard of Arixtra syringes, some batches had been quarantined, leading to shortages of the 1.5, 2.5, 5.0 and 7.5 mg strengths of Arixtra pre-filled syringes.• The defect means that when the needle guard is pulled off, it may leave behind the inner needle shield.• Healthcare professionals will receive detailed guidance on how to remove the retained needle shield.

¹ This information may change. For up-to-date information about the status of a medicine shortage in a particular Member State, contact the national competent authority.



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	<ul style="list-style-type: none">• The defect does not affect the safety and efficacy of Arixtra.• The quarantined batches have now been released and it is expected that the shortage will be resolved.• Additional advice may be available from the national competent authority.
Information for patients	<ul style="list-style-type: none">• Because of a minor defect affecting the protective needle guard of Arixtra syringes, some batches had not been released, leading to shortages of certain strengths (1.5, 2.5, 5.0 and 7.5 mg) of Arixtra.• The affected batches have now been released, which will resolve the shortage.• In the meantime, other strengths of Arixtra or alternative medicines are available that could be used instead.• There are no problems with the safety and effectiveness of Arixtra.• Patients who have any questions should speak to their doctor or pharmacist.• Additional advice may be available from the national competent authority.