



European Medicines Agency

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PUBLIC STATEMENT ON

Quixidar (fondaparinux sodium)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

The Marketing Authorisation Holder (MAH) responsible for Quixidar, Glaxo Group Ltd notified the European Commission on 11 February 2008 of its decision to voluntarily withdraw the marketing authorisation for Quixidar for commercial reasons.

Quixidar is indicated for:

1.5 mg/0.3 ml and 2.5 mg/0.5 ml, solution for injection:

Prevention of Venous Thromboembolic Events (VTE) in patients 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 patients undergoing abdominal surgery who are judged to be at high risk of thromboembolic complications, such as patients undergoing abdominal cancer surgery (see section 5.1).

Prevention of Venous Thromboembolic Events (VTE) in 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.

2.5 mg/0.5 ml, solution for injection

Treatment of unstable angina or non-ST segment elevation myocardial infarction (UA/NSTEMI) in patients for whom urgent (< 120 mins) invasive management (PCI) is not indicated (see sections 4.4 and 5.1).

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

5 mg/0.4 ml, 7.5 mg/0.6 ml and 10 mg/0.8 ml solution for injection:

Treatment of 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.

Quixidar was never marketed in the European Union. Arixtra is an identical product available in the European Union.

On 11 March 2008, the European Union issued a decision to withdraw the marketing authorisation for Quixidar. Pursuant to this decision, the European Public Assessment Report (EPAR) for Quixidar will be updated to reflect that the marketing authorisation is no longer valid.

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of Medicinal Products for Human Use