European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

QUIXIDAR

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Quixidar?
Quixidar is a solution for injection in a prefilled syringe.
Quixidar contains the active substance fondaparinux sodium (1.5, 2.5, 5, 7.5 or 10 mg per syringe).

What is Quixidar used for?
Quixidar (1.5 and 2.5 mg strengths) is used to prevent venous thromboembolic events (VTEs, problems caused by blood clots) in patients who are having major surgery to their legs, such as a hip replacement or surgery to repair a knee or hip fracture. It can also be used in patients at high risk (because of their age or disease) when they have abdominal surgery, especially for cancer, or when they are forced to stay in bed because of an acute illness.
At higher strengths (5, 7.5 and 10 mg), Quixidar is used to treat VTEs such as deep vein thrombosis (DVT, a blood clot in the leg) or pulmonary embolism (PE, blood clot in the lung).
The 2.5 mg strength is also used to treat patients with unstable angina (a type of chest pain that changes in severity) or who are having a myocardial infarction (heart attack):

- without 'ST segment elevation' (an abnormal reading on the electrocardiogram or ECG) in patients who are not going to undergo urgent angioplasty (within two hours): angioplasty or 'percutaneous coronary intervention' (PCI) is an operation to unblock the heart's blood vessels,
- with 'ST segment elevation' in patients who are receiving thrombolytic medicines ('clot busters') or who are not about to receive any other treatment to restore blood flow to the heart.

The medicine can only be obtained with a prescription.

How is Quixidar used?
In the prevention of VTEs, the recommended dose of Quixidar is 2.5 mg once a day by subcutaneous injection (under the skin). For patients having surgery, the first dose should be given six hours after the end of the operation. Treatment should be continued until the risk of VTE has been reduced, usually at least five to nine days after surgery. For patients who have kidney problems, Quixidar may not be suitable, or the lower 1.5-mg dose may be used.
In the treatment of DVT or PE, the recommended dose is 7.5 mg once a day by subcutaneous injection, usually for seven days. The dose may be adjusted, depending on body weight.
For patients with unstable angina or myocardial infarction, the recommended dose is 2.5 mg once daily by subcutaneous injection, but the first dose is given intravenously (into a vein) through an existing line or as an infusion (drip) in patients with ST segment elevation. Treatment should be

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started as soon as possible after diagnosis and continued for up to eight days or until the patient is discharged from hospital. Quixidar is not recommended in patients who are about to undergo certain types of PCI.
For more information, see the Summary of Product Characteristics (also part of the EPAR).

How does Quixidar work?
Blood clotting can be a problem when blood flow is disturbed in any way. Quixidar is an anticoagulant; it prevents the blood from coagulating (clotting). The active ingredient in Quixidar, fondaparinux sodium, stops one of the substances (factors) that are involved in the clotting of blood, Factor Xa. When this is blocked, no thrombin (another factor) can be produced, and no clot can be formed. By using Quixidar after surgery, the risk of a blood clot forming is greatly reduced. By reducing blood clots, Quixidar can also help the flow of blood to the heart to be maintained in patients with angina or who are having a heart attack.

How has Quixidar been studied?
The effectiveness of Quixidar has been studied for the prevention of and in the treatment of VTE. In the prevention studies, Quixidar was compared with other anticoagulants: enoxaparin (in hip or knee surgery; over 8,000 patients) or dalteparin (in abdominal surgery; 2,927 patients). It was also compared with placebo (a dummy treatment) when looking at patients with an acute illness (839 patients) and patients treated for an additional 24 days following hip fracture surgery (656 patients). In the treatment of VTE, Quixidar was compared with enoxaparin (DVT: 2,192 patients) or with unfractionated heparin (PE: 2,184 patients). In all studies, the main measure of effectiveness was the overall rate of thrombotic events (problems caused by blood clots).
Quixidar has also been studied in two main studies of patients with unstable angina or myocardial infarction. The first compared the effects of Quixidar with those of enoxaparin in over 20,000 patients with unstable angina or myocardial infarction without ST segment elevation, and the second compared Quixidar with standard care (unfractionated heparin in eligible patients, or placebo) in over 12,000 patients with myocardial infarction with ST segment elevation. The main measure of effectiveness was the proportion of patients who died or had an 'ischaemic event' (restriction of blood supply to an organ, including the heart).

What benefit has Quixidar shown during the studies?
The overall rate of thrombotic events in patients treated with Quixidar was significantly less than in patients treated with placebo or enoxaparin (for patients undergoing leg surgery), and was similar to that seen with enoxaparin (treatment of DVT), dalteparin or unfractionated heparin.
Quixidar was at least as effective as enoxaparin in preventing death or an ischaemic event in patients with unstable angina or myocardial infarction without ST segment elevation, with around 5% of the patients in each group had died or had an ischaemic event after nine days. In the study of myocardial infarction with ST segment elevation, Quixidar reduced the risk of death or another heart attack by 14% after 30 days, compared to standard care. However, these results were insufficient to show whether Quixidar was more effective than unfractionated heparin or not.

What is the risk associated with Quixidar?
As with other antithrombotic medicines, the most common side effect of Quixidar is bleeding. For the full list of all side effects reported with Quixidar, see the Package Leaflet.
Quixidar should not be used in people who may be hypersensitive (allergic) to fondaparinux sodium or any of the other ingredients, who might be bleeding already, who have acute bacterial endocarditis (an infection of the heart) or have severe kidney problems. For the full list of restrictions, see the Package Leaflet.

Why has Quixidar been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Quixidar's benefits are greater than its risks in both the prevention and the treatment of VTEs, unstable angina and myocardial infarction. The Committee recommended that Quixidar be given marketing authorisation.

Other information about Quixidar:
The European Commission granted a marketing authorisation valid throughout the European Union for Quixidar on 21 March 2002. The marketing authorisation was renewed on 21 March 2007. The marketing authorisation holder is Glaxo Group Ltd.

The full EPAR for Quixidar can be found here.

This summary was last updated in 09-2007.