HAUTE AUTORITÉ DE SANTÉ

CARDIOLOGY
Update
March 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

ARIXTRA 1.5 mg (fondaparinux), anticoagulant

Still insufficient clinical benefit in thromboprophylaxis in the absence of robust efficacy and safety data in patients with renal failure

Main points

- ARIXTRA 1.5 mg/0.3 mL has marketing authorisation in adults in the prevention of venous thromboembolism:
- in major orthopaedic surgery of the lower limb (hip fracture, hip replacement, major knee surgery);
- in abdominal surgery, in patients considered at high risk for thromboembolic complications (abdominal surgery for cancer);
- in patients considered at high risk for venous thromboembolic complications and bedridden due to an acute medical condition (heart failure, acute respiratory failure, infectious or inflammatory disease);
and in the treatment of symptomatic spontaneous acute superficial vein thrombosis of the lower limbs, with no associated deep vein thrombosis.
- This low dose has marketing authorisation as a dose adjustment of the 2.5 mg dosage only in patients with moderate to severe renal failure (CrCl between 20 and 50 mL/min).
- Given the lack of robust efficacy and safety data in case of renal failure, its role in the therapeutic strategy cannot be established.

Therapeutic strategy

- After major orthopaedic surgery of the lower limb and in patients at risk of a venous thromboembolic (VTE) event following abdominal surgery or bedridden due to an acute medical condition, an anticoagulant is recommended. This thromboprophylaxis is carried out either by injection (LMWH, UFH or fondaparinux switched to an AVK), or by oral treatment (dabigatran, rivaroxaban, apixaban). The choice between these medicinal products takes into account, in particular, the risk of haemorrhage, the risk of lower efficacy (UFH in particular) and the absence of long-term safety data (apixaban, dabigatran, rivaroxaban). The duration of this thromboprophylaxis varies, and can be extended beyond 10-14 days and up to 35 days following hip fracture.
- Mechanical means are recommended in combination with medical treatment, as well as in case of contraindication to anticoagulant drug treatment.
- **Role of the proprietary medicinal product in the therapeutic strategy**

  Given the lack of robust clinical data demonstrating its antithrombotic efficacy in subjects at risk of overexposure to fondaparinux and therefore at risk of haemorrhage, ARIXTRA 1.5 mg has no role in thromboprophylaxis or in the treatment of deep venous thrombosis in patients with renal failure.

Clinical data

- There are still no clinical data with a good level of evidence demonstrating the efficacy of the 1.5 mg dosage in the indications of ARIXTRA 1.5 mg.

Benefit of the medicinal product

- The actual clinical benefit* of ARIXTRA 1.5 mg/0.3 mL is insufficient for reimbursement by National Health Insurance in the indications of the marketing authorisation.
- Does not recommend inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 22 March 2017 (CT-15789) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the ACB, which can be substantial, moderate, low or insufficient for reimbursement of the medicinal product for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV (equivalent to “no CAV”) means “no clinical added value”.