



TRANSPARENCY COMMITTEE

SUMMARY

08 JULY 2020

The legally binding text is the original French opinion version

rivaroxaban

XARELTO 10 mg, 15 mg and 20 mg film-coated tablets

Reevaluation

► Key points

Favourable opinion for maintenance of reimbursement in the MA indications.

► Role in the care pathway?

The role of XARELTO (rivaroxaban) in the care pathway remains unchanged for all its indications. In the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrences, the Committee considers that XARELTO (rivaroxaban) still has no role in patients with active cancer, including in patients at low haemorrhagic risk, due to a lack of sufficient clinical data.

COMMITTEE'S CONCLUSIONS

Clinical benefit

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrences

- ▶ Venous thromboembolic disease is one of the leading causes of cardiovascular death. It is a serious disease that can be life-threatening (potentially fatal pulmonary embolism) or have serious sequelae (post-thrombotic syndrome).
- ▶ This is a curative and preventive treatment.
- ▶ The efficacy/adverse effects ratio of rivaroxaban remains high in the treatment of DVT and PE, and the prevention of their recurrences. Its assessment beyond 12 months of treatment is only documented in comparison with placebo.
- ▶ There are several medicinal alternatives, including in the event of long-term treatment and in patients with active cancer.
- ▶ XARELTO (rivaroxaban) remains a first-line treatment in the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrences. It should be noted that, in the absence of sufficient data, XARELTO (rivaroxaban) still has no role in the subpopulation of patients with active cancer.

▶ Public health impact:

On the basis of currently available data, the previous assessment of the PHI is not modified: XARELTO (rivaroxaban) is unlikely to have an additional impact on public health in this indication compared to other oral anticoagulants.

Considering all these elements, the Committee deems that the clinical benefit of XARELTO (rivaroxaban) remains substantial in treatment of DVT and PE and the prevention of their recurrences, including in the event of long-term treatment.

The Committee issues a favourable opinion for maintenance of inclusion in the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and dosages.

Prevention of stroke and systemic embolism in NVAf

- ▶ Atrial fibrillation (AF) is the most common cardiac rhythm disorder. It increases with age. The leading cause of cerebral embolism of cardiac origin, it is responsible for around 50% of ischaemic strokes. Non-valvular atrial fibrillation (NVAf) is life-threatening for patients, either immediately or following complications, such as stroke, which is characterised by its severity and significantly impairs quality of life.
- ▶ This is a preventive treatment.
- ▶ The efficacy/adverse effects ratio of rivaroxaban remains high in this indication.
- ▶ There are therapeutic alternatives, including VKAs and the other three direct-acting oral anticoagulant (DOACs).
- ▶ This is a first-line treatment in this indication when the prescription of an anticoagulant is considered.

► Public health impact:

On the basis of currently available data, the previous assessment of the PHI is not modified: XARELTO (rivaroxaban) is unlikely to have an additional impact on public health in this indication compared to other oral anticoagulants.

Considering all these elements, the Committee deems that the clinical benefit of XARELTO (rivaroxaban) remains substantial in this indication.

The Committee issues a favourable opinion for maintenance of inclusion in the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and dosages.

Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery

► Venous thromboembolic disease is a serious disease that can be life-threatening to patients (potentially fatal pulmonary embolism) or have serious sequelae (post-thrombotic syndrome).

► This is a preventive treatment.

► The efficacy/adverse effects ratio of rivaroxaban in this indication is high.

► There are several medicinal alternatives, administered orally or by injection.

► This is a first-line treatment.

► Public health impact:

On the basis of currently available data, the previous assessment of the PHI is not modified: XARELTO (rivaroxaban) is unlikely to have an additional impact on public health in this indication compared to other oral anticoagulants.

Considering all these elements, the Committee deems that the clinical benefit of XARELTO (rivaroxaban) remains substantial in this indication.

The Committee issues a favourable opinion for maintenance of inclusion in the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and dosages.