HAUTE AUTORITÉ DE SANTÉ

ASSESSING HEALTH TECHNOLOGIES

OPINION RELATIVE TO MEDICINAL PRODUCTS

apixaban

ELIQUIS 2.5 mg - 5 mg

Film-coated tablets

Re-evaluation

Adopted by the Transparency Committee on 15 June 2022

SUMMARY

The legally binding text is the original French opinion version

- **Antithrombotic agent**
- **Sectors: Retail and hospital**

Role in the care pathway?

The Committee considers that ELIQUIS (apixaban) is a first-line therapeutic option in the treatment of DVT/PE, and prevention of their recurrence in patients with active cancer.

The presence of progressive cancer or cancer under treatment is considered to be a major persistent risk factor for recurrence of a thromboembolic event; patients have a 4 to 7 times greater risk of developing VTE. Thrombosis is the second leading cause of death in cancer patients, after disease progression[Erreur ! Signet non défini.].

For short-term treatment (up to 10 days), all the injectable antithrombotic agents with a marketing authorisation (MA) can be used. Only dalteparin and tinzaparin have an MA and are funded in the extended treatment of symptomatic VTE and prevention of recurrences in patients with active cancer and/or on chemotherapy. Vitamin K antagonists (VKAs) are also authorised for extended treatment in active cancer patients, following heparin therapy.

For the first 6 months, it is recommended that DVT or PE be treated using low molecular weight heparin (LMWH), without subsequent VKA therapy. The decision to continue treatment beyond 6 months is taken on a case-by-case basis depending, in particular, on the cancer location, the concomitant treatment (presence or otherwise of chemotherapy), the presence or otherwise of a recurrence in the first 6 months and tolerance to the treatment.

The risk/benefit ratio of continuing anticoagulant therapy will be reassessed regularly for any treatment lasting more than 6 months.

Role of the medicinal product in the care pathway

Considering new data available in the treatment of DVT/PE, and prevention of their recurrence in patients with active cancer, based on two randomised comparative phase 3 studies versus dalteparin (CARAVAGGIO and ADAM VTE), and, in particular:

- robust demonstration of a non-inferior efficacy of apixaban at 6 months compared to dalteparin, the reference treatment, with respect to the prevention of VTE recurrences,
- a satisfactory safety profile as regards the risk of major bleeding, in the absence of an additional risk observed with apixaban in comparison with dalteparin in the two studies, but a possibly increased risk of clinically relevant non-major bleeding with apixaban,

The Committee considers that ELIQUIS (apixaban) is a first-line therapeutic option in the treatment of DVT/PE, and prevention of their recurrence in patients with active cancer.

When apixaban is envisaged as treatment for DVT or PE in patients with active cancer, a rigorous assessment of the benefits compared to the risks should be conducted.

In particular, the Committee highlights the fact that the increased risk of recurrences of VTE with apixaban compared to dalteparin suggested in subjects over 75 years of age in the CARAVAGGIO study should encourage caution in this subpopulation. The possibly increased risk of clinically relevant non-major bleeding with apixaban should also be taken into account.

The Committee reiterates that apixaban has not been evaluated in the extended treatment of VTE associated with active cancer for periods of beyond 6 months.

The Summary of Product Characteristics (SPC) and the Risk Management Plan (RMP) must be complied with.