25 July 2024
EMA/284159/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Axitinib Accord

axitinib

On 25 July 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Axitinib Accord, intended for the treatment of adult patients with renal cell carcinoma (RCC).

The applicant for this medicinal product is Accord Healthcare S.L.U.

Axitinib Accord will be available as 1 mg, 3 mg and 5 mg film-coated tablets. The active substance of Axitinib Accord is axitinib, an antineoplastic agent, protein kinase inhibitor (ATC code: L01EK01). Axitinib inhibits vascular endothelial growth factor receptors (VEGFR)-1, VEGFR-2 and VEGFR-3.

Axitinib Accord is a generic of Inlyta, which has been authorised in the EU since 3 September 2012. Studies have demonstrated the satisfactory quality of Axitinib Accord, and its bioequivalence to the reference product Inlyta. A question and answer document on generic medicines can be found here.

The full indication is:

> Axitinib Accord is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) after failure of prior treatment with sunitinib or a cytokine.

Treatment with Axitinib Accord should be conducted by a physician experienced in the use of anticancer therapies.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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