15 September 2022
EMA/CHMP/758392/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sorafenib Accord

sorafenib

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sorafenib Accord, intended for the treatment of hepatocellular carcinoma and renal cell carcinoma. The applicant for this medicinal product is Accord Healthcare S.L.U.

Sorafenib Accord will be available as a 200 mg film-coated tablet. The active substance of Sorafenib Accord is sorafenib, a protein kinase inhibitor (ATC code: L01EX02). It inhibits the activity of targets present in tumour cells and in the tumour vasculature.

Sorafenib Accord is a generic of Nexavar, which has been authorised in the EU since 19 July 2006. Studies have demonstrated the satisfactory quality of Sorafenib Accord and its bioequivalence to the reference product Nexavar. A question and answer document on generic medicines can be found here.

The full indication is:

> Hepatocellular carcinoma
>
> Sorafenib Accord is indicated for the treatment of hepatocellular carcinoma (see section 5.1).
>
> Renal cell carcinoma
>
> Sorafenib Accord is indicated for the treatment of patients with advanced renal cell carcinoma who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.

Sorafenib Accord should be prescribed by a physician experienced in the treatment of cancer.

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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