10 December 2020
EMA/CHMP/635286/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sunitinib Accord

sunitinib

On 10 December 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sunitinib Accord, intended for the treatment of cancer. The applicant for this medicinal product is Accord Healthcare S.L.U.

Sunitinib Accord will be available as 12.5, 25, 37.5 and 50 mg hard capsules. The active substance of Sunitinib Accord is sunitinib, an antineoplastic agent – a protein-tyrosine kinase inhibitor (ATC code: L01XE04), which inhibits multiple receptor tyrosine kinases that are implicated in tumour growth, pathologic angiogenesis, and metastatic progression of cancer.

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

The full indication is:

> Sunitinib Accord is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.
>
> Sunitinib Accord is indicated for the treatment of advanced/metastatic renal cell carcinoma (MRCC) in adults.
>
> Sunitinib Accord is indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults.

Sunitinib Accord should be prescribed by physicians 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

[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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