26 January 2023
EMA/CHMP/30821/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tolvaptan Accord

tolvaptan

On 26 January 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tolvaptan Accord, intended for the treatment of low blood sodium levels in adults secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH). The applicant for this medicinal product is Accord Healthcare S.L.U.

Tolvaptan Accord will be available as 7.5 mg, 15 mg and 30 mg tablets. The active substance of Tolvaptan Accord is tolvaptan, a diuretic and vasopressin antagonist (ATC code: C03XA01). By blocking the vasopressin V2 receptor, tolvaptan increases urine production, resulting in a decrease in the amount of water in the blood and an increase of the blood sodium level.

Tolvaptan Accord is a generic of Samsca, which has been authorised in the EU since 03 August 2009. Studies have demonstrated the satisfactory quality of Tolvaptan Accord, and its bioequivalence to the reference product Samsca. A question and answer document on generic medicines can be found here.

The full indication is:

> Tolvaptan is indicated in adults for the treatment of hyponatremia secondary to the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

Due to the need for a dose titration phase with close monitoring of serum sodium and volume status, treatment with tolvaptan has to be initiated in hospital.

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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