23 July 2026
EMADOC-1829012207-57965
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tafamidis Accord

tafamidis

On 23 July 2026 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the granting of a marketing authorisation for the medicinal product Tafamidis Accord, intended for the treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy.

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

Tafamidis Accord will be available as 61 mg capsules. The active substance of Tafamidis Accord is tafamidis (ATC code: N07XX08), a selective stabilizer of transthyretin tetramer.

Tafamidis Accord is a generic of Vyndaqel, which has been authorised in the EU since 16 November 2011. Studies have demonstrated the satisfactory quality of Tafamidis Accord, and its bioequivalence to the reference product Vyndaqel.

The full indication is:

Tafamidis Accord is indicated for the treatment of hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTRh-CM).

Tafamidis Accord should be initiated under the supervision of a physician knowledgeable in the management of patients with amyloidosis or cardiomyopathy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website 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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