12 November 2026
EMADOC-1829012207-78499
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Baxfendy

baxdrostat

On 12 November 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 Baxfendy, intended for the treatment of insufficiently controlled hypertension.

The applicant for this medicinal product is AstraZeneca AB.

Baxfendy will be available as 1 mg and 2 mg film-coated tablets. The active substance of Baxfendy is baxdrostat, an antihypertensive (ATC code: C02KN02). Baxdrostat is a selective inhibitor of human aldosterone synthase. Aldosterone contributes to hypertension by promoting renal sodium and water retention, which increases blood volume, and by acting directly on the blood vessels to promote dysfunction, inflammation and fibrosis.

The benefits of Baxfendy are clinically relevant and statistically significant reductions in systolic and diastolic blood pressure in patients with uncontrolled high blood pressure despite the use of at least two blood pressure-lowering medicinal products, as observed in randomised, double-blind, placebo-controlled studies.

The most common side effect with baxdrostat is hyperkalaemia.

The full indication is:

> BAXFENDY is indicated for the treatment of adult patients with arterial hypertension insufficiently controlled with at least two antihypertensive medicinal products (see section 5.1).

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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