21 May 2026
EMADOC-1700519818-3115823
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Fasenra

benralizumab

On 21 May 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Fasenra. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a new indication as follows:[2]

Asthma

Fasenra is indicated as an add-on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long-acting β-agonists (see section 5.1).

Eosinophilic granulomatosis with polyangiitis (EGPA)

Fasenra is indicated as an add-on treatment for adult patients with relapsing or refractory eosinophilic granulomatosis with polyangiitis (see section 5.1).

Hypereosinophilic syndrome (HES)

Fasenra is indicated as an add-on treatment for adult and adolescent patients aged 12 years and older weighing at least 35 kg with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause (see section 4.2 and 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

[2] New text in bold.

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