



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2024
EMA/422937/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Fasenra

benralizumab

On 19 September 2024, 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 an extension to the existing indication as follows:

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).

For information, the full indications for Fasenra will be 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).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to 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

² New text in bold

