17 September 2026
EMADOC-1829012207-69309
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Adcomfo

omalizumab

On 17 September 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 Adcomfo, intended for the treatment of severe persistent allergic asthma, chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic spontaneous urticaria (CSU).

The applicant for this medicinal product is Advanz Pharma Limited.

Adcomfo will be available as a 75 mg, 150 mg and 300 mg solution for injection in pre-filled syringe or pre-filled pen. The active substance of Adcomfo is omalizumab, a drug for obstructive airway diseases (ATC code: R03DX05). Omalizumab is a recombinant DNA-derived humanised monoclonal antibody that selectively binds to human immunoglobulin E (IgE), thereby reducing the amount of free IgE available to trigger the allergic cascade.

Adcomfo is a biosimilar medicinal product. It is highly similar to the reference product Xolair (omalizumab), which was authorised in the EU on 25 October 2005. Data show that Adcomfo has comparable quality, safety and efficacy to Xolair (omalizumab). More information on biosimilar medicines can be found here.

The full indication is:

> Allergic asthma
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> ADCOMFO is indicated in adults, adolescents and children (6 to <12 years of age).
>
> ADCOMFO treatment should only be considered for patients with convincing IgE (immunoglobulin E) mediated asthma (see section 4.2).
>
> *Adults and adolescents (12 years of age and older)*
>
> ADCOMFO is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and who have reduced lung function (FEV_1 <80%) as well as frequent daytime

[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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symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Children (6 to <12 years of age)

ADCOMFO is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and frequent daytime symptoms or night-time awakenings and who have had multiple documented severe asthma exacerbations despite daily high-dose inhaled corticosteroids, plus a long-acting inhaled beta2-agonist.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

ADCOMFO is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe CRSwNP for whom therapy with INC does not provide adequate disease control.

Chronic spontaneous urticaria (CSU)

ADCOMFO is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

Adcomfo should be prescribed by physicians experienced in the treatment of severe persistent asthma, CRSwNP or CSU.

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.