16 September 2021
EMA/CHMP/2165/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Nucala

Mepolizumab

On 16 September 2021, 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 Nucala. The marketing authorisation holder for this medicinal product is GlaxoSmithKline Trading Services Limited.

The CHMP adopted three new indications[2]. For information, the full indications for Nucala will be as follows:

Severe eosinophilic asthma

Nucala is indicated as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older.

Eosinophilic granulomatosis with polyangiitis (EGPA)

Nucala is indicated as an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA).

Hypereosinophilic syndrome (HES)

Nucala is indicated as an add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause.

Chronic rhinosinusitis with nasal polyps

Nucala is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

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

[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**

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

(EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.