



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 July 2018
EMA/CHMP/489705/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Nucala

mepolizumab

On 26 July 2018, 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 an extension to the existing indication as follows²:

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

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 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.

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

