



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/CHMP/57839/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Stelara ustekinumab

On 27 February 2025, 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 Stelara. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted an extension to an existing indication to extend the use of Stelara to children with Crohn's disease weighing at least 40 kg. The change will apply to Stelara concentrate for solution for infusion and solution for injection in vial or pre-filled syringe, as follows:

Paediatric Crohn's Disease

STELARA is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients weighing at least 40 kg, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy.

For information, the full indications for Stelara will be available in the updated summary of product characteristics (SmPC).

Detailed recommendations for the use of this product will be described in the updated 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 Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

