



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 February 2026  
EMADOC-1700519818-2938344  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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# Stelara

## ustekinumab

On 26 February 2026 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.

The CHMP adopted a change to the existing indication as follows:<sup>2</sup>

### Paediatric Crohn's disease

STELARA is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients **from the age of 2 years and older**, ~~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 now be:

### Plaque psoriasis

STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A) (see section 5.1).

### Paediatric plaque psoriasis

STELARA is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies (see section 5.1).

### Psoriatic arthritis (PsA)

STELARA, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease modifying anti

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<sup>1</sup> Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold, removed text as strikethrough



rheumatic drug (DMARD) therapy has been inadequate (see section 5.1).

#### Adult Crohn's disease

STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF $\alpha$  antagonist.

#### Paediatric Crohn's disease

STELARA is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients from the age of 2 years and older, who have had an inadequate response to, or were intolerant to either conventional or biologic therapy.

#### Ulcerative colitis

STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (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.