



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2024
EMA/153422/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Wezenla

ustekinumab

On 25 April 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Wezenla, intended for the treatment of plaque psoriasis, including paediatric plaque psoriasis, psoriatic arthritis and Crohn's disease in adults.

The applicant for this medicinal product is Amgen Technology (Ireland) UC.

Wezenla will be available as 45 and 90 mg solution for injection and 130 mg concentrate for solution for infusion. The active substance of Wezenla is ustekinumab, an immunosuppressant interleukin inhibitor (ATC code: L04AC05). Ustekinumab is a human IgG1 κ monoclonal antibody that binds to the p40 protein subunit shared by interleukin-12 (IL-12) and IL-23. By doing so, it prevents them from binding to the IL 12R β 1 receptor protein expressed on the surface of immune cells. Ustekinumab may therefore exert its clinical effects in psoriasis, psoriatic arthritis and Crohn's disease through inhibition of the Th1 and Th17 cytokine pathways, which are central to the pathology of these diseases.

Wezenla is a biosimilar medicinal product. It is highly similar to the reference product Stelara (ustekinumab), which was authorised in the EU on 15 January 2009. Data show that Wezenla has comparable quality, safety and efficacy to Stelara. More information on biosimilar medicines can be found [here](#).

The full indication is:

Plaque psoriasis

WEZENLA 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

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



WEZENLA 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)

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

Crohn's disease

WEZENLA 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 α antagonist or have medical contraindications to such therapies.

WEZENLA should be prescribed by physicians experienced in the treatment of the conditions for which it is indicated.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.