18 September 2025
EMA/292179/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Usgena

ustekinumab

On 18 September 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Usgena, intended for the treatment of adults and children with plaque psoriasis, and adults with psoriatic arthritis, Crohn's disease and ulcerative colitis.

The applicant for this medicinal product is STADA Arzneimittel AG.

Usgena will be available as a 45 mg solution for injection in a vial or pre-filled syringe, a 90 mg solution for injection in one or two pre-filled syringes and a 130 mg concentrate for solution for infusion in a vial. The active substance of Usgena is ustekinumab, an immunosuppressant interleukin inhibitor (ATC code: L04AC05). Ustekinumab is a fully human IgG1κ monoclonal antibody that binds to the shared p40 protein subunit of interleukin (IL) 12 and 23, thereby preventing them from binding to the IL-12Rβ1 receptor protein expressed on the surface of immune cells. By doing so, ustekinumab prevents the activation of the Th1 and Th17 cytokine pathways, which are central to the pathology of psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis.

Usgena 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 Usgena has comparable quality, safety and efficacy to Stelara. More information on biosimilar medicines can be found here.

The full indications are:

> Plaque psoriasis
>
> Usgena 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

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

Usgena 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)

Usgena, 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

Usgena 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 TNFα antagonist.

Ulcerative colitis

Usgena 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.

Usgena is intended for use under the guidance and supervision of physicians experienced in the diagnosis and treatment of the conditions for which the medicine is indicated.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.