11 December 2025
EMADOC-1829012207-36858
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Gotenfia

golimumab

On 11 December 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 Gotenfia, intended for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, axial spondyloarthritis and ulcerative colitis. The applicant for this medicinal product is STADA Arzneimittel AG.

Gotenfia will be available as a 50 mg and 100 mg solution for injection in pre-filled syringes. The active substance of Gotenfia is golimumab, a tumour necrosis factor alpha (TNF-α) inhibitor (ATC code: L04AB06). Golimumab is a human monoclonal antibody that forms high affinity, stable complexes with both the soluble and transmembrane bioactive forms of human TNF-α, which prevents the binding of TNF-α to its receptors. By blocking TNF-α, golimumab reduces the inflammation and other symptoms of the diseases it is used for.

Gotenfia is a biosimilar medicinal product. It is highly similar to the reference product Simponi (golimumab), which was authorised in the EU on 1 October 2009. Data show that Gotenfia has comparable quality, safety and efficacy to Simponi. More information on biosimilar medicines can be found here.

The full indication is:

Rheumatoid arthritis (RA)

Gotenfia, in combination with methotrexate (MTX), is indicated for:

- the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease-modifying anti-rheumatic drug (DMARD) therapy including MTX has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX.

[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

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Golimumab, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.

Juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis (pJIA)

Gotenfia in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children 2 years of age and older, who have responded inadequately to previous therapy with MTX.

Psoriatic arthritis (PsA)

Gotenfia, alone or in combination with MTX, is indicated for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. Golimumab has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease (see section 5.1) and to improve physical function.

Axial spondyloarthritis

Ankylosing spondylitis (AS)

Gotenfia is indicated for the treatment of severe, active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

Non-radiographic axial spondyloarthritis (nr-Axial SpA)

Gotenfia is indicated for the treatment of adults with severe, active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

Ulcerative colitis (UC)

Gotenfia is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

Treatment with Gotenfia is to be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, or ulcerative colitis. Patients treated with Gotenfia should be given the Patient Card.

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.