17 September 2026
EMADOC-1829012207-57671
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Inijaq

tofacitinib

On 17 September, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Inijaq, intended for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis and juvenile idiopathic arthritis.

The applicant for this medicinal product is Gedeon Richter Plc.

Inijaq will be available as a 5 mg film-coated tablets. The active substance of Inijaq is tofacitinib, a immunosuppressant, Janus-associated kinase (JAK) inhibitor (ATC code: L04AF01). Tofacitinib preferentially inhibits JAK1 and JAK3. This reduces signalling by several interleukins (IL-2, IL-4, IL-6, IL-7, IL-9, IL-15 and IL-21), as well as type I and type II interferons, thereby modulating immune and inflammatory responses.

Inijaq is a generic of Xeljanz, which has been authorised in the EU since 22 March 2017. Studies have demonstrated the satisfactory quality of Inijaq, and the company has provided data supporting bioequivalence to Xeljanz. A question and answer document on generic medicines can be found here.

The full indication is:

> Rheumatoid arthritis
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> Tofacitinib in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs (DMARDs) (see section 5.1).
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> Tofacitinib can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate (see sections 4.4 and 4.5).
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> Psoriatic arthritis
>
> Tofacitinib in combination with MTX is indicated for the treatment of active psoriatic arthritis

[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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(PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy (see section 5.1).

Ankylosing spondylitis

Tofacitinib is indicated for the treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy.

Ulcerative colitis

Tofacitinib is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent (see section 5.1).

Juvenile idiopathic arthritis (JIA)

Tofacitinib is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), and juvenile psoriatic arthritis (PsA) in patients 2 years of age and older, who have responded inadequately to previous therapy with DMARDs.

Tofacitinib can be given in combination with methotrexate (MTX) or as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Inijaq should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which tofacitinib 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.