26 February 2026
EMADOC-1829012207-42079
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tuyory

tocilizumab

On 26 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tuyory, intended for the treatment of rheumatoid arthritis (RA), coronavirus disease 2019 (COVID-19), systemic juvenile idiopathic arthritis (sJIA), polyarticular juvenile idiopathic arthritis (pJIA), CAR-T cell-induced severe or life-threatening cytokine release syndrome (CRS), and giant cell arteritis (GCA).

The applicant for this medicinal product is Gedeon Richter Plc.

Tuyory will be available as a 20 mg/ml concentrate for solution for infusion and a 162 mg solution for injection in pre-filled syringe or pre-filled pen. The active substance of Tuyory is tocilizumab, an interleukin inhibitor (ATC code: L04AC07). Tocilizumab is a recombinant humanised anti-human interleukin-6 receptor (IL-6R) monoclonal antibody of the immunoglobulin IgG1 subclass. It works by inhibiting soluble and membrane-bound interleukin-6 receptors implicated in the pathogenesis of inflammatory diseases.

Tuyory is a biosimilar medicinal product. It is highly similar to the reference product RoActemra (tocilizumab), which was authorised in the EU on 16 January 2009. Data show that Tuyory has comparable quality, safety and efficacy to RoActemra. More information on biosimilar medicines can be found here.

The full indication for Tuyory 20 mg/ml concentrate for solution for infusion is:

> Rheumatoid arthritis (RA)
>
> Tuyory, in combination with methotrexate (MTX), is indicated for:
>
> - the treatment of severe, active and progressive RA in adults not previously treated with MTX.
> - the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more

[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

disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, Tuyory can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

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

Coronavirus disease 2019 (COVID-19)

Tuyory is indicated for the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

Systemic juvenile idiopathic arthritis (sJIA)

Tuyory is indicated for the treatment of active sJIA in patients 2 years of age and older, who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tuyory can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

Polyarticular juvenile idiopathic arthritis (pJIA)

Tuyory in combination with MTX is indicated for the treatment of pJIA (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. Tuyory can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Cytokine release syndrome (CRS)

Tuyory is indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening CRS in adults and paediatric patients 2 years of age and older.

The full indication for Tuyory 162 mg solution for injection in pre-filled syringe is:

Rheumatoid arthritis (RA)

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

- the treatment of severe, active and progressive RA in adults not previously treated with MTX.
- the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, Tuyory can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Tocilizumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

Systemic juvenile idiopathic arthritis (sJIA)

Tuyory is indicated for the treatment of active sJIA in patients 1 year of age and older, who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tuyory can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

Polyarticular juvenile idiopathic arthritis (pJIA)

Tuyory in combination with MTX is indicated for the treatment of pJIA (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. Tuyory can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Giant cell arteritis (GCA)

Tuyory is indicated for the treatment of GCA in adult patients.

The full indication for Tuyory 162 mg solution for injection in pre-filled pen is:

Rheumatoid arthritis (RA)

Tuyory, in combination with methotrexate (MTX), is indicated for

- the treatment of severe, active and progressive RA in adults not previously treated with MTX.
- the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, Tuyory can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Tocilizumab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

Systemic juvenile idiopathic arthritis (sJIA)

Tuyory is indicated for the treatment of active sJIA in patients 12 years of age and older, who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids.

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

Polyarticular juvenile idiopathic arthritis (pJIA)

Tuyory in combination with methotrexate (MTX) is indicated for the treatment of pJIA (rheumatoid factor positive or negative and extended oligoarthritis) in patients 12 years of age and older, who have responded inadequately to previous therapy with MTX.

Tuyory can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Giant cell arteritis (GCA)

Tuyory is indicated for the treatment of GCA in adult patients.

Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA, COVID-19, sJIA, pJIA, CGA or CRS.

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.