



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 September 2026
DOCID
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Jyseleca filgotinib

On 17 September 2026 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Jyseleca. The marketing authorisation holder for this medicinal product is Alfasigma S.p.A.

The CHMP adopted a new indication as follows:

Axial spondyloarthritis

Non-radiographic axial spondyloarthritis (nr-axSpA)

Jyseleca is indicated for the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).

Ankylosing spondylitis (AS, radiographic axial spondyloarthritis [r-axSpA])

Jyseleca is indicated for the treatment of active ankylosing spondylitis (radiographic axial spondyloarthritis) in adult patients who have responded inadequately to conventional therapy.

For information, the full indications for Jyseleca will be as follows:²

Rheumatoid arthritis

Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX).

Ulcerative colitis

¹ Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold



Jyseleca 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 agent.

Axial spondyloarthritis

Non-radiographic axial spondyloarthritis (nr-axSpA)

Jyseleca is indicated for the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).

Ankylosing spondylitis (AS, radiographic axial spondyloarthritis [r-axSpA])

Jyseleca is indicated for the treatment of active ankylosing spondylitis (radiographic axial spondyloarthritis) in adult patients who have responded inadequately to conventional therapy.

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

