24 July 2025
EMA/226344/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Taltz

ixekizumab

On 24 July 2025, 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 Taltz. The marketing authorisation holder for this medicinal product is Eli Lilly and Co (Ireland) Limited.

The CHMP adopted a new indication as follows:

Juvenile idiopathic arthritis (JIA)

Juvenile psoriatic arthritis (JPsA)

Taltz, alone or in combination with methotrexate, is indicated for the treatment of active JPsA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Enthesitis-related arthritis (ERA)

Taltz, alone or in combination with methotrexate, is indicated for the treatment of active ERA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy.

For information, the full indications for Taltz will be as follows:[2]

Plaque psoriasis

Taltz is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Paediatric plaque psoriasis

Taltz is indicated for the treatment of moderate to severe plaque psoriasis in children from the age of 6 years and with a body weight of at least 25 kg and adolescents who are candidates for systemic therapy.

[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
[2] New text in bold

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Psoriatic arthritis

Taltz, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies (see section 5.1).

Axial spondyloarthritis

Ankylosing spondylitis (radiographic axial spondyloarthritis)

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

Non-radiographic axial spondyloarthritis

Taltz is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis 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).

Juvenile idiopathic arthritis (JIA)

Juvenile psoriatic arthritis (JPsA)

Taltz, alone or in combination with methotrexate, is indicated for the treatment of active JPsA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, conventional therapy.

Enthesitis-related arthritis (ERA)

Taltz, alone or in combination with methotrexate, is indicated for the treatment of active ERA in patients 6 years of age and older and with a body weight of at least 25 kg, who have had an inadequate response to, or who are intolerant of, 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.