



15 October 2020
EMA/CHMP/535466/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Tremfya

guselkumab

On 15 October 2020, 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 Tremfya. The marketing authorisation holder for this medicinal product is Janssen-Cilag International N.V.

The CHMP adopted a new indication in psoriatic arthritis. For information, the full indications for Tremfya will be as follows²:

Plaque psoriasis

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

Psoriatic arthritis

Tremfya, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis 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).

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

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 as **bold**

