



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2019
EMA/CHMP/476189/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Remsima infliximab

On 19 September 2019, 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 Remsima. The marketing authorisation holder for this medicinal product is Celltrion Healthcare Hungary Kft.

The CHMP recommended approval of a new route of administration, strength and pharmaceutical form: Remsima 120 mg solution for injection for subcutaneous use in prefilled pens or syringes. This pharmaceutical form will be available in addition to the existing one: 100 mg, powder for concentrate for solution for infusion.

Remsima for subcutaneous use is authorised only in the rheumatoid arthritis indication.

The full indication for Remsima for subcutaneous use is as follows:

“Rheumatoid arthritis

Remsima, in combination with methotrexate, is indicated for the reduction of signs and symptoms as well as the improvement in physical function in:

- adult patients with active disease when the response to disease-modifying antirheumatic drugs (DMARDs), including methotrexate, has been inadequate.
- adult patients with severe, active and progressive disease not previously treated with methotrexate or other DMARDs.

In these patient populations, a reduction in the rate of the progression of joint damage, as measured by X-ray, has been demonstrated (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

