EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2018
EMA/CHMP/833171/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Simponi

golimumab

On 13 December 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending changes to the terms of the marketing authorisation for the medicinal product Simponi. The marketing authorisation holder for this medicinal product is Janssen Biologics B.V.

The CHMP adopted an extension to one of the existing indications for Simponi 50 mg solution for injection in pre-filled pens and syringes as follows:[2]

> "Juvenile idiopathic arthritis
>
> Polyarticular juvenile idiopathic arthritis (pJIA)
>
> Simponi in combination with MTX is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children **2 years of age and older** ~~with a body weight of at least 40 kg~~, who have responded inadequately to previous therapy with MTX."

In addition, the CHMP recommended approval of a new formulation of Simponi, a 45 mg/0.45 ml solution for injection in pre-filled pens, for the above indication.

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 in bold, removed text as strikethrough

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