21 July 2016
EMA/CHMP/486928/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Orencia

abatacept

On 21 July 2016, 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 Orencia. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted a new indication for Orencia in combination with methotrexate as follows:

> "the treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate."

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

> "Rheumatoid arthritis
>
> Orencia, in combination with methotrexate, is indicated for:
>
> - the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who responded inadequately to previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) including methotrexate (MTX) or a tumour necrosis factor (TNF)-alpha inhibitor
> - **the treatment of highly active and progressive disease in adult patients with rheumatoid arthritis not previously treated with methotrexate."**
>
> A reduction in the progression of joint damage and improvement of physical function have been demonstrated during combination treatment with abatacept and methotrexate.
>
> Polyarticular juvenile idiopathic arthritis
>
> Orencia in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (JIA) in paediatric patients 6 years of age and older who have had an insufficient response to other DMARDs including at least one TNF inhibitor.

[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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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.