



31 January 2019
EMA/CHMP/917551/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Orencia abatacept

On 31 January 2019, 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 Orencia. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted a new indication for Orencia 50, 87.5 and 125 mg solution for injection in pre-filled syringe as follows:

"Polyarticular juvenile idiopathic arthritis

Orencia in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) in paediatric patients 2 years of age and older who have had an inadequate response to previous DMARD therapy.

Orencia can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate."

The CHMP also adopted a change to an existing indication for Orencia 250 mg powder for concentrate for solution for infusion as follows:²

"Polyarticular juvenile idiopathic arthritis

Orencia in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) in paediatric patients 6 years of age and older who have had an ~~insufficient~~ **inadequate** response to ~~other DMARDs including at least one~~ ~~TNF inhibitor~~ previous DMARD therapy.

Orencia can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate."

For information, the full indications for Orencia 50, 87.5 and 125 mg solution for injection in pre-filled syringe will be as follows:

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



"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.

Psoriatic arthritis

Orencia, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients when the response to previous DMARD therapy including MTX has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required.

Polyarticular juvenile idiopathic arthritis

Orencia in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) in paediatric patients 2 years of age and older who have had an inadequate response to previous DMARD therapy.

Orencia can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate."

For information, the full indications for Orencia 250 mg powder for concentrate for solution for infusion will be as follows:

"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.

Psoriatic Arthritis

Orencia, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients when the response to previous DMARD therapy including MTX has been inadequate, and for whom additional systemic therapy for psoriatic skin lesions is not required.

Polyarticular juvenile idiopathic arthritis

Orencia in combination with methotrexate is indicated for the treatment of moderate to severe active polyarticular juvenile idiopathic arthritis (pJIA) in paediatric patients 6 years of age and older who have had an inadequate response to previous DMARD therapy.

Orencia can be given as monotherapy in case of intolerance to methotrexate or when treatment with methotrexate is inappropriate.”

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.