



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 October 2021  
EMA/578657/2021  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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# Zeposia

## ozanimod

On 14 October 2021, 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 Zeposia. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

The CHMP adopted an extension to the existing indication as follows:<sup>2</sup>

Multiple sclerosis

Zeposia is indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features.

**Ulcerative colitis** Zeposia is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold

