



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 September 2026
EMADOC-1700519818-3443099
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Ocrevus ocrelizumab

On 17 September 2026, 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 Ocrevus. The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to an existing indication as follows:²

Ocrevus is indicated for the treatment of adult patients **and paediatric patients aged 10 years and older** with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features (see section 5.1).

For information, the full indications for Ocrevus will be as follows:

Ocrevus is indicated for the treatment of adult patients and paediatric patients aged 10 years and older with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features (see section 5.1).

Ocrevus is indicated for the treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity (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 on EMA website 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.

