



30 March 2023  
EMA/CHMP/101113/2023  
Committee for Medicinal Products for Human Use (CHMP)

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

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# Ultomiris

## ravulizumab

On 30 March 2023, 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 Ultomiris. The marketing authorisation holder for this medicinal product is Alexion Europe SAS.

The CHMP adopted a new indication to include treatment of adults with AQP4-positive neuromyelitis optica spectrum disorder (NMOSD).

For information, the full indications for Ultomiris will therefore be as follows:<sup>2</sup>

Ultomiris is indicated in the treatment of adult and paediatric patients with a body weight of 10 kg or above with PNH:

- in patients with haemolysis with clinical symptom(s) indicative of high disease activity.
- in patients who are clinically stable after having been treated with eculizumab for at least the past 6 months (see section 5.1).

Ultomiris is indicated in the treatment of patients with a body weight of 10 kg or above with aHUS who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab (see section 5.1).

Ultomiris is indicated as an add-on to standard therapy for the treatment of adult patients with gMG who are anti-acetylcholine receptor (AChR) antibody-positive.

**Ultomiris is indicated in the treatment of adult patients with NMOSD who are anti-aquaporin 4 (AQP4) antibody-positive (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 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

