



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2022
EMA/CHMP/637630/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Ultomiris ravulizumab

On 21 July 2022, 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 for the treatment of generalised myasthenia gravis. For information, the full indication will therefore be as follows:²

Paroxysmal nocturnal haemoglobinuria (PNH)

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).

Atypical haemolytic uremic syndrome (aHUS)

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).

Generalized myasthenia gravis (gMG)

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.

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.

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**

