30 March 2023
EMA/CHMP/111122/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

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 recommended the addition of a new pharmaceutical form (solution for injection in a cartridge) associated with a new strength (245 mg) to be administered subcutaneously via an on-body injector.

The full indications for the new formulation of Ultomiris will be as follows:

- the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (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.
- the treatment of adult patients with atypical haemolytic uremic syndrome (aHUS) who are complement inhibitor treatment-naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab.

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

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