



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 September 2011  
EMA/CHMP/771662/2011  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Soliris eculizumab

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Soliris. The marketing authorisation holder for this medicinal product is Alexion Europe SAS. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:  
"Atypical hemolytic uremic syndrome (aHUS)".

Detailed conditions 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 the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication(s) for Soliris will be as follows<sup>2</sup>:

Soliris (eculizumab) is indicated for the treatment of patients with:

- Paroxysmal nocturnal haemoglobinuria (PNH).  
Evidence of clinical benefit of Soliris in the treatment of patients with PNH is limited to patients with history of transfusions.
- **Atypical hemolytic uremic syndrome (aHUS)** (see section 5.1)

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

<sup>2</sup> The text in bold represents the new or the amended indication.

