14 April 2011
EMA/CHMP/306613/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Carbaglu

(carglumic acid)

On 14 April 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 Carbaglu. The marketing authorisation holder for this medicinal product is Orphan Europe S.A.R.L. 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 new indications as follows:

"Carbaglu is indicated in treatment of

- **hyperammonaemia due to isovaleric acidaemia;**
- **hyperammonaemia due to methymalonic acidaemia;**
- **hyperammonaemia due to propionic acidaemia".**

The CHMP adopted an amendment to *an existing indication* as follows[2]:

"Carbaglu is indicated in treatment of

- hyperammonaemia due to N-acetylglutamate synthase **primary** deficiency"

For information, the full indications for Carbaglu will be as follows[2]:

"Carbaglu is indicated in treatment of

- hyperammonaemia due to N-acetylglutamate synthase **primary** deficiency;
- **hyperammonaemia due to isovaleric acidaemia;**
- **hyperammonaemia due to methymalonic acidaemia;**
- **hyperammonaemia due to propionic acidaemia".**

[1] 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.

[2] The text in bold represents the new or the amended indication.

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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.