



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms
of the marketing authorisation

International non-proprietary name: betaine anhydrous

Procedure No. EMEA/H/C/PSUSA/00000390/201502

Period covered by the PSUR: 1 March 2014 – 28 February 2015



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for betaine anhydrous, the scientific conclusions of CHMP are as follows:

Cerebral oedema is listed as a potential important risk for betaine anhydrous. During this reporting period, a new case of brain oedema was reported in a patient with cystathionine beta-synthase (CBS) deficiency. Cumulatively, a total of six cases of brain oedema were reported. A review of these cases showed that only this subpopulation of patients with CBS deficiency treated with betaine anhydrous present a risk of hypermethioninemia, associated with brain oedema.

Therefore, in view of the available data, the PRAC considered that changes to the product information were warranted. The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for betaine anhydrous the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing betaine anhydrous is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisations should be varied.