24 September 2015
EMA/713568/2015
Committee for Medicinal Products for Human Use (CHMP)

Carbaglu

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

International non-proprietary name: carglumic acid

Procedure No.: EMEA/H/C/PSUSA/00000564/201501

Period covered by the PSUR: 01 February 2010 - 31 January 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Carbaglu is authorised for oral use. During the period covered by this PSUR, 4 cases of incorrect administration of Carbaglu by intravenous infusion have been identified, one of which had a fatal outcome. When considering these cases, the PRAC noted that there is the potential for certain wording in the summary of product characteristics (SmPC) and/or in the patient leaflet to be misinterpreted as it mentions administration by syringe but does not unequivocally clarify that Carbaglu is for oral administration only. Therefore the PRAC considered that this information should be added to the relevant sections of the SmPC, labelling and package leaflet.

Following the reprocessing of cases using a new methodology as requested in the recent pharmacovigilance inspection, 9 events of 'rash' which occurred in 2 patients were identified in the safety database. On the basis of this information, the PRAC agreed on the need to list this adverse reaction in the product information.

Therefore, in view of available data regarding rash and cases of incorrect route of administration, 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 carglumic acid the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing carglumic acid is favourable subject to the proposed changes to the product information

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