EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 May 2018
EMA/554096/2018
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): sodium oxybate (oral use)

Procedure No. EMEA/H/C/PSUSA/00010612/201710

Period covered by the PSUR: 13-Oct-2016 to 12-Oct-2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for sodium oxybate (oral use), the scientific conclusions of the CHMP are as follows:

During the reporting interval, 24 cases (non-serious) of nocturia with a cumulative of 321 cases (4 serious) were reported. There were 8 medically confirmed cases reporting nocturia with compatible chronology and/or positive dechallenge and/or positive rechallenge. Among them, there were 6 cases with compatible chronology ranging from 1 day to 30 days, including 2 of them with a reported positive dechallenge.

Based on an overall review and assessment of the safety data and considering the number of cases demonstrating potential temporal association of the event of nocturia, relevant dechallenge and rechallenge with sodium oxybate, and possible biological plausibility increased fluid intake due to salt content and solute diuresis from salt load, the PRAC considered that a causal relationship between the use of sodium oxybate and the occurrence of nocturia could not be excluded. Therefore, the product information of sodium oxybate (oral use) containing products should be updated to include ‘nocturia’ with a frequency not known in section 4.8 of the SmPC and in the package leaflet.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing sodium oxybate (oral use) were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for sodium oxybate (oral use) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sodium oxybate (oral use) is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.