EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2015
EMA/CHMP/196751/2015
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:aclidinium bromide, micronised

Procedure No. EMEA/H/C/PSUSA/00009005/201407

Period covered by the PSUR: 21.01.14 - 20.07.14

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 aclidinium bromide, micronised, the scientific conclusions of CHMP are as follows:

During the reporting period cases of nausea, stomatitis and dizziness have been observed. There was a sufficient number of positive dechallenges in all cases to consider that a causal relationship between the medicinal product and the adverse event is at least a reasonable possibility. A number of cases and complaints relating to the feel of the product were also received during the reporting interval.

Therefore, in view of available data regarding aclidinium bromide and the risk of nausea, dizziness and stomatitis as well as the number of cases of “product taste abnormal”, 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 aclidinium bromide, micronised the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing aclidinium bromide, micronised is favourable subject to the proposed changes to the product information

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