EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2015
EMA/19569/2016
Committee for Medicinal Products for Human Use (CHMP)

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

Active substance: agomelatine

International non-proprietary name: Valdoxan; Thymanax

Procedure No: EMEA/H/C/PSUSA/00000071/201502

Period covered by the PSUR: 20 February 2014 to 19 February 2015

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Scientific conclusions

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

84 cases of confusional state/disorientation have been reported cumulatively. There are two well-documented cases of delirium, both with positive rechallenge. Additionally, there is substantial number of events that are timely related to the initiation of treatment with agomelatine and with positive dechallenge.

Therefore, in view of available data regarding confusional state, 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 agomelatine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing agomelatine is favourable subject to the proposed changes to the product information

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