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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: lurasidone

Procedure No. EMEA/H/C/PSUSA/00010114/201410

Period covered by the PSUR: 28 April 2014 – 27 October 2014

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Scientific conclusions

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

Cumulatively there have been 26 spontaneous cases (9 in this reporting period) of neuroleptic malignant syndrome (NMS) reported with lurasidone. There was a temporal association and a biological plausibility and there were positive dechallenges in most of the cases where information was available. Based on this data the PRAC concluded that NMS should be included as an adverse drug reaction in the product information.

Therefore, in view of available data regarding lurasidone, 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 lurasidone the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing lurasidone is favourable subject to the proposed changes to the product information

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