EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): lurasidone

Procedure No. EMEA/H/C/PSUSA/00010114/201504

Period covered by the PSUR: 28 October 2014 – 27 April 2015

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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 in this PSUR there were 239 reported events of tardive dyskinesia and related symptoms associated with the use of lurasidone, of which 19 were serious. There were 116 spontaneous cases reporting Preferred Term (PT) tardive dyskinesia. The temporal association of the events of tardive dyskinesia to lurasidone treatment and a biological plausibility further support an update of the product information, where tardive dyskinesia should be added as an adverse reaction. Based on the placebo-controlled clinical studies the frequency category was identified as uncommon.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing lurasidone 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 lurasidone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lurasidone is favourable subject to the proposed changes to the product information

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