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/00010114/201610

Period covered by the PSUR: 28 October 2015 to 28 October 2016

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Scientific conclusions

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

Hyponatremia:

Hyponatremia has been reported in clinical trials (5 serious adverse events (SAEs) and 13 non-serious adverse events (AE)) and post-marketing (13 SAEs and 12 non-serious AEs). Considering the totality of data presented, the PRAC agrees that a causal association between hyponatremia and the use of lurasidone is a reasonable possibility, and as such hyponatremia should be considered an adverse drug reaction (ADR) with lurasidone with frequency uncommon.

Hypersensitivity:

Based on the additional data provided by the MAH on the number of subjects with one or more treatment emergent hypersensitivity adverse events, the PRAC agrees to change the frequency of the ADRs hypersensitivity, rash and pruritus from not known to common, and to change frequency of angioedema from not known to rare.

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

Grounds for 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(s) containing lurasidone 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.