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Committee for Medicinal Products for Human Use (CHMP)

Latuda

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

International non-proprietary name: LURASIDONE

Procedure No. EMEA/H/C/002713/PSUV/0002

Period covered by the PSUR: 28 October 2013 – 27 April 2014

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Scientific conclusions

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

Based on the review of cases from clinical trials and post-marketing safety reports containing events captured under the term “hypersensitivity”, there were 5 cases where the causal role for lurasidone was considered likely. Two of the cases involved serious allergic reaction with symptoms of throat and tongue swelling, 1 case involved serious facial angioedema and 2 nonserious cases of urticarial rash. Therefore the PRAC concluded that the adverse reaction hypersensitivity should be included 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 Latuda, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance 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.