25 September 2014
EMA/CHMP/654103/2014
Committee for Medicinal Products for Human Use (CHMP)

Lojuxta

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

International non-proprietary name: lomitapide

Procedure No. EMEA/H/C/002578/PSUV/0008

Period covered by the PSUR: 31 July 2013 – 31 January 2014

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Scientific conclusions

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

The MAH has reviewed the categorisation of the CYP 3A4 inhibitors ritonavir and tipranavir. Ritonavir and tipranavir are currently listed in section 4.5 of the SmPC as weak CYP3A4 inhibitors. Ritonavir is primarily used as a pharmacokinetic enhancer. All recommended combinations with ritonavir should be labelled as moderate or strong inhibitors according to the University of Washington database. As the concomitant use of moderate or strong CYP3A4 inhibitors with Lojuxta is contraindicated, Lojuxta should not be combined with ritonavir or ritonavir-enhanced highly active antiretroviral therapy (HAART) for HIV. Although tipranavir as monotherapy may be classified as an inducer and an inhibitor of cytochrome CYP3A, it should always be co-administered with ritonavir as a enhancer and at the recommended dosage. There is a potent net inhibition of CYP3A. There is no need to mention this combination of drugs specifically, as ritonavir boosted HAART includes therapy with tipranavir/ritonavir. Ritonavir and tipranavir are therefore both strong inhibitors and the PRAC agreed to remove them from the list of weak CYP3A4 inhibitors in section 4.5 of the SmPC.

Therefore, in view of available data regarding the CYP3A4 inhibitors ritonavir and tipranavir, 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 Lojuxta, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance lomitapide is favourable subject to the proposed changes to the product information.

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