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): telbivudine

Procedure No. EMEA/H/C/PSUSA/00002880/201608

Period covered by the PSUR: 01 September 2013 to 31 August 2016

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Scientific conclusions

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

Based on a cumulative review submitted by the MAH with this PSUR, a total of 96 cases of lactic acidosis was reported with telbivudine, including 54 cases as a secondary event of a serious underlying conditions, such as rhabdomyolysis or myopathy and 26 cases with no evident primary causes, although CPK elevation were often associated. Moreover, one literature case report of severe refractory lactic acidosis was reported during the review period in a patient receiving telbivudine monotherapy and for whom no underlying serious conditions was reported. In cumulative, seven fatal cases of lactic acidosis were recorded including six cases where lactic acidosis was reported as a symptom or secondary to rhabdomyolysis. Overall, it is acknowledged that it remains difficult to clearly conclude whether lactic acidosis causes muscle events or lactic acidosis follows muscular damage.

Based on the available evidence, the PRAC considered that that the telbivudine SmPC should be updated to reinforce the current warning in section 4.4 of the SmPC on lactic acidosis, notably by highlighting the potential fatal outcome of telbivudine-induced lactic acidosis in a context of rhabdomyolysis and to delete the current information in section 4.8 of the SmPC that lactic acidosis has been reported with telbivudine exclusively as a secondary event (since it is not always the case).

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing telbivudine were warranted.

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 telbivudine the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing telbivudine is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.