14 September 2023
EMA/395778/2023
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): abacavir / lamivudine / zidovudine

Procedure No. EMEA/H/C/PSUSA/00003144/202212

Period covered by the PSUR: 01/01/2020 To: 31/12/2022

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for abacavir / lamivudine / zidovudine, the scientific conclusions of PRAC are as follows:

In view of available data on cardiovascular events from the literature regarding abacavir, including a plausible mechanism of action, the PRAC considers that the warnings and precautions for use of products containing abacavir need to be revised to adequately reflect the current level of information on cardiovascular events and, in line with the current therapeutic guidelines, that a recommendation discouraging the use of abacavir containing products in patients with high cardiovascular risk should also be included in the product information. The PRAC concluded that the product information of products containing abacavir/ lamivudine/ zidovudine should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for abacavir / lamivudine / zidovudine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing abacavir / lamivudine / zidovudine 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.