EMA/470525/2020
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): dolutegravir, dolutegravir / abacavir / lamivudine, dolutegravir / lamivudine

Procedure No. EMEA/H/C/PSUSA/00010075/202001

Period covered by the PSUR: 17/07/2019 to 16/01/2020

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Scientific conclusions

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

In view of data from the publication by Waitt et al. 2019 regarding the transfer of dolutegravir into breast milk, the PRAC concluded that the product information of products containing dolutegravir should be amended with this updated information. It should be noted, that the package leaflet of both Dovato and Triumeq already include the following sentence: *A small amount of the ingredients in Dovato/Triumeq can also pass into your breast milk.* Therefore, these leaflets do not need to be updated in this regard.

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

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

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