EMA/540739/2018
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): cobicistat / elvitegravir / emtricitabine / tenofovir alafenamide

Procedure No. EMEA/H/C/PSUSA/00010449/201805

Period covered by the PSUR: 05 November 2017 to 04 May 2018

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for cobicistat / elvitegravir / emtricitabine / tenofovir alafenamide, the scientific conclusions of CHMP are as follows:

Based on two reports received of altered mental state with impairment in speech, gait, tremor although with limited information (both reporting potential cobicistat FDC and lurasidone interaction), a contraindication with lurasidone due to CYP3A inhibition with cobicistat was identified in medicinal products containing cobicistat / elvitegravir / emtricitabine / tenofovir alafenamide and therefore the PRAC agreed that the product information should be updated accordingly.

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 cobicistat / elvitegravir / emtricitabine / tenofovir alafenamide, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing cobicistat / elvitegravir / emtricitabine / tenofovir alafenamide is unchanged subject to the proposed changes to the product information.

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