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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): cobicistat

Procedure No. EMEA/H/C/PSUSA/00010081/201708

Period covered by the PSUR: 27 August 2016 to 26 August 2017

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Scientific conclusions

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

Increased levels of lurasidone, such as in overdose, is potentially associated with cardiac arrhythmias due to QT prolongation, seizures and cardiovascular collapse. The Latuda (lurasidone) SmPC currently contraindicates coadministration with cobicistat, and cobicistat containing products Symtuza and Rezolsta include contraindications for lurasidone, however, these CIs are not included in the product information for Evotaz, Genvoya, Stribild or Tybost. Given the potentially serious nature of the interaction and the fact the contraindication is already included in several cobicistat containing product information, it is considered appropriate to also specifically include the contraindication in the Tybost SmPC.

Update of sections 4.3 and 4.5 of the SmPC to add the contraindication/warning of co-administration with lurasidone. The Package leaflet is updated accordingly.

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 cobicistat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cobicistat 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.