



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): raltegravir

Procedure No. EMEA/H/C/PSUSA/00010373/202009

Period covered by the PSUR: 26 September 2019 to 26 September 2020



Scientific conclusions

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

In view of available data on the risk of DDI with iron salts, including the publication from Rajesh 2016, and James et al 2020, and as per other INSTIs and other metal cations such as aluminium or magnesium (for which co-administration is not recommended), the PRAC Rapporteur considers that there is a risk of drug-drug interaction with iron salts, which is also a metal cation, and consequently a potential risk of virologic failure because of the relatively low genetic barrier for RTG. It is therefore recommended that the product information of products containing raltegravir is amended to recommend staggered administration as a risk minimisation measure.

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