



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): sirolimus

Procedure No. EMEA/H/C/PSUSA/00002710/202009

Period covered by the PSUR: 15 September 2017 to 14 September 2020



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for sirolimus, the scientific conclusions of CHMP are as follows:

In view of available data on drug/drug interaction from cumulative review including two cases reported to the MAH's global safety database and in view of one human pharmacokinetic study, the PRAC concluded that 'Other possible interactions' of section 4.5 of the SmPC should be updated to add the interaction between sirolimus and letermovir. 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 sirolimus the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing sirolimus is unchanged subject to the proposed changes to the product information.

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