10 November 2022
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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): cabotegravir

Procedure No. EMEA/H/C/PSUSA/00010900/202203

Period covered by the PSUR: 18/09/2021 To: 17/03/2022

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific conclusions

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

In view of available data on the reports including ten cases of hypersensitivity reactions with close causal relationship to cabotegravir intake, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between cabotegravir and "hypersensitivity" is at least a reasonable possibility. The PRAC concluded that the product information of products containing cabotegravir should be amended 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 cabotegravir the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing cabotegravir is unchanged subject to the proposed changes to the product information

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