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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): oritavancin

Procedure No. EMEA/H/C/PSUSA/00010368/202003

Period covered by the PSUR: 20/03/2019 To: 19/03/2020

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Annex IV

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Scientific conclusions

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

In view of available data on infusion related reactions from clinical trial(s), and spontaneous reports and considering that reported cases have a close temporal relationship, a positive de-challenge and in some cases positive re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between oritavancin and chest pain/discomfort, chills, back pain, dyspnoea, fever, tremor, hypoxia, neck pain and abdominal pain are at least a reasonable possibility. The PRAC concluded that the product information of product containing oritavancin 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 oritavancin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing oritavancin 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.