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: oritavancin

Procedure No. EMEA/H/C/PSUSA/00010368/201709

Period covered by the PSUR: from 20 March 2017 to 19 September 2017

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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:

Following evaluation of the available evidence, the marketing authorisation holder updated sections 4.4 and 4.8 of the SmPC with regards to the signal on “Red Man Syndrome” (RMS). 25 case reports were analysed in the context of the signal. Out of these 25 reports: 11 showed clear evidence of RMS and 9 showed questionable evidence of RMS. The remaining 5 contained insufficient information for an adequate assessment. The package leaflet is updated accordingly.

The strong structural similarities between oritavancin and vancomycin would argue that the occurrence of RMS in oritavancin-treated patients would not be unexpected. The most compelling characteristic present in all these reports, is the similar description of the adverse events experienced and their resemblance to the definition of RMS. Each of these cases contained reports of rash, flushing and/or “redness” of the neck, face and/or upper back. The time of occurrence was highly variable, ranging from 5 minutes into the infusion to occurring at the end of a 3-hr infusion. Previous exposure would present the confounding consideration that the adverse events experienced might be hypersensitivity reactions, which are part of the established side effect profile of oritavancin.

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.