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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/00010368/201903

Period covered by the PSUR: 20 Sep 2018 to 19 March 2019

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

Section 4.4 of the Oritavancin SmPC includes a warning concerning risk of hypersensitivity reactions, to monitor early symptoms of such reactions and to take appropriate actions if necessary. Hypersensitivity reactions are listed in the section 4.8. However, further SmPC and PL update is considered necessary to add information about the risk of anaphylactic reactions and anaphylactic shock.

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.