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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): voriconazole

Procedure No. EMEA/H/C/PSUSA/00003127/201802

Period covered by the PSUR: 01-Mar-2017 to 28-Feb-2018

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Scientific conclusions

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

Three key cases of drug reaction with eosinophilia and systemic symptoms (DRESS) were identified that support a probable association between voriconazole use and DRESS. One of the reports described a definite DRESS case according to RegiScar criteria and a positive re-challenge when voriconazole was re-introduced. Two other cases concerned probable drug reaction with eosinophilia and systemic symptoms (DRESS) according to RegiScar criteria and patients experienced recovery after voriconazole withdrawal.

Having considered the evidence from published case reports, and taken into account the seriousness of the adverse drug reaction, the MAH is requested to update the product information of voriconazole to add drug reaction with eosinophilia and systemic symptoms (DRESS) with a frequency rare and to add a warning on drug reaction with eosinophilia and systemic symptoms (DRESS).

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 voriconazole the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing voriconazole 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.