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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): ketoconazole (centrally authorised product only)

Procedure No. EMEA/H/C/PSUSA/00010316/201611

Period covered by the PSUR: 20 May 2016 to 19 November 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for ketoconazole (centrally authorised product only), the scientific conclusions of CHMP are as follows:

Ketoconazole is a potent inhibitor of CYP3A4 enzyme and P-gp transporter. Pharmacokinetics of medicines that are substrates of CYP3A4 and P-gp can be affected when administered concomitantly with ketoconazole, potentially leading to serious adverse drug reactions (ADRs) and/or need for dose adjustment of these medicinal products. The PRAC considers that, in view of the available data the interaction of ketoconazole with edoxaban and isavuconaziole should be added to the product information.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing ketoconazole were warranted.

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 ketoconazole (centrally authorised product only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ketoconazole (centrally authorised product only) 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.