



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 December 2015  
EMA/CHMP/41543/2016  
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/00010316/201505

Period covered by the PSUR: 19 November 2014 – 19 May 2015



## **Scientific conclusions**

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

Ketoconazole is a potent inhibitor of CYP3A4 enzyme. Pharmacokinetics of medicines that are substrates of CYP3A4 can be affected when administered concomitantly with ketoconazole, potentially leading to clinically significant serious Adverse Drug Reactions (ADRs) and/or the need for dose adjustment of these medicinal products. PRAC considers that, in view of the available data the interaction of ketoconazole with CYP3A4 substrates should be added to the product information.

Therefore, in view of the data presented in the reviewed PSUR(s), 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.