EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/332925/2021
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): posaconazole

Procedure No. EMEA/H/C/PSUSA/00002480/202010

Period covered by the PSUR: 26/10/2017 To: 25/10/2020

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

Scientific conclusions

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

In view of available data in the literature reporting a compelling case with a compatible chronology, a plausible pharmacological mechanism and a positive de-challenge where hypercalcaemia occurred when posaconazole and ATRA were combined and normalized when posaconazole was stopped, the PRAC considers it important to monitor ATRA's side effects when it is used in combination with drugs inhibiting the cytochrome P450 enzymes. The PRAC concluded that the product information of products containing posaconazole should be amended accordingly.

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