EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/00003127/202102

Period covered by the PSUR: 01 March 2018 to 28 February 2021

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Scientific conclusions

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

In view of available data on spontaneous reports including cases with a close temporal relationship, and current labelling on SCC, the PRAC Rapporteur considers a causal relationship between voriconazole and cutaneous SCC, or Bowen's disease is at least a reasonable possibility. In order to increase the knowledge of voriconazole risks, additional wording regarding Bowen's disease should be included in sections 4.4 and 4.8 of the SmPC to reinforce the level of awareness of physicians.

During the current reporting interval, there were 28 cases reporting 28 serious events matching the search criteria for SCC and corresponding to 0.5% of total PM cases compared to 20 cases (1.0%) in the previous reporting interval. Out of these 28 SCC cases, there were 4 Bowen's disease cases. (also see Table 11 on page 28 of this AR).

Based on the 4 additional Bowen's disease cases reported during this interval (26 cumulatively) the MAHs should amend/further specify the current labelling on SCC following post-marketing reports of Bowen's disease. Cumulatively, 26 reports of Bowen's disease, which is a distinct clinical-pathologic variant of SCC in situ were identified. Considering that Bowen's disease and invasive SCC represent different steps within the disease continuum of squamous neoplasia, but also that the incidence of Bowen's disease is similar to SCC in the general population, these cases may suggest under-reporting of these reactions. A disproportionality was found for the PT "Bowen's disease" from EVDAS, ROR (-) = 32.35 cumulatively.

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.