



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2022
EMA/669852/2022
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): isavuconazole

Procedure No. EMEA/H/C/PSUSA/00010426/202109

Period covered by the PSUR: 06/09/2020 to 06/09/2021



Scientific conclusions

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

In view of available data on anaphylactic reaction from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC Rapporteur considers a causal relationship between isavuconazole and anaphylactic reaction is at least a reasonable possibility. The PRAC concluded that the product information of products containing isavuconazole should be amended accordingly.

Update of section 4.4 and 4.8 of the SmPC to add the adverse reaction anaphylactic reaction with a frequency not known and a warning on anaphylactic reaction. The Package leaflet is updated 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 isavuconazole the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing isavuconazole is unchanged subject to the proposed changes to the product information