EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 April 2026
EMADOC-1700519818-3246926
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): rezafungin

Procedure No. PSUSA/00000221/202509

Period covered by the PSUR: 22 March 2025 to 21 September 2025

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 An agency of the European Union

Scientific conclusions

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

In view of available data on anaphylactic reaction from spontaneous reports including a close temporal relationship and a positive de-challenge, and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between rezafungin and anaphylactic reaction is at least a reasonable possibility. The PRAC therefore concluded that the product information of products containing rezafungin should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for rezafungin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing rezafungin 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.