12 October 2023
EMA/448724/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rezzayo

rezafungin

On 12 October 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rezzayo[2], intended for the treatment of invasive candidiasis in adults. The applicant for this medicinal product is Mundipharma GmbH.

Rezzayo will be available as a 200 mg powder for concentrate for solution for infusion. The active substance of Rezzayo is rezafungin, an antimycotic for systemic use (ATC code: J02AX08). Rezafungin selectively inhibits the fungal enzyme 1,3-β-D-glucan synthase, inhibiting formation of 1,3-β-D-glucan, an essential component of the fungal cell wall. This, in turn, results in rapid and concentration-dependent fungicidal activity in *Candida* species (spp.).

The benefit of Rezzayo is that it is as effective as caspofungin in the treatment of invasive candidiasis, as shown in a phase 3, randomised, double-blind, non-inferiority study. The most common side effects are hypokalaemia, pyrexia, and diarrhoea.

The full indication is:

> REZZAYO is indicated for the treatment of invasive candidiasis in adults.

Rezzayo should be prescribed by physicians experienced in the management of invasive fungal infections.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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