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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): caspofungin

Procedure No. PSUSA/00000576/202412

Period covered by the PSUR:
3 years to 12 December 2024

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Scientific conclusions

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

In view of available data on caspofungin treatment failure during continuous renal replacement therapy (CRRT) with polyacrylonitrile (PAN) membranes from the literature, spontaneous reports (including in five cases a close temporal relationship and fatal outcomes), and in view of a plausible mechanism of action (adsorption of the free drug fraction by PAN membranes leading to subtherapeutic exposure), the PRAC considers a causal relationship between caspofungin and treatment failure during CRRT with PAN membranes is at least a reasonable possibility. The PRAC concluded that the product information of products containing caspofungin 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(s)

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