

Annex I

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for caspofungin, the scientific conclusions of the 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.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Summary of Product Characteristics
(new text **underlined and in bold**, deleted text ~~strike through~~)

- Section 4.4

A warning should be added as follows:

Use during renal replacement therapy (RRT)

In patients receiving caspofungin during continuous RRT, the use of polyacrylonitrile-derived membranes (e.g., during hemofiltration or hemodiafiltration) may result in adsorption of the drug, potentially reducing caspofungin efficacy. Increasing the dose may not prevent this effect. It is recommended to use an alternative extracorporeal membrane, or another antifungal agent. The risk of treatment failure may result in worsening infection and death.