

DOCUMENT

T.R. MINISTRY OF HEALTH Turkish Medicines and Medical Devices Agency
Number: E-24931227-510.01.04-5825389 22.01.2026 Subject:
About Drugs Containing Caspofungin/Emergency Safety Restriction/Opinion-Contribution
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1 | 2

FILE

Regarding caspofungin-containing drugs, the European Medicines Agency's (EMA) warning that "the use of polyacrylonitrile-based membranes during continuous renal replacement therapy may reduce the effectiveness of caspofungin" has been evaluated by your Agency and the attached statements must be added to the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) of these drugs.

Your opinions, recommendations and contributions, if any, regarding the decision taken must be submitted to the Pharmacovigilance Risk Management Unit of the Pharmacovigilance and Controlled Substances Department within 15 days, and no application be made to the Pharmacological Evaluation Unit of the Department of Medicinal Products Marketing Authorization within this period.

I kindly request that you are informed and perform the required action.

Prof. Dr. Ahmet AYAR

Head of the Agency

Annex: SmPC-PIL text (1 page)

Distribution Requirement:

Pharmaceutical Manufacturers Association of Turkey

Association of Research-Based Pharmaceutical Companies

Pharmaceutical Industry Association of Turkey

Association of Healthcare Products

Pharmaceutical Industry and Technologies Commission

Association of Innovative Pharmaceutical Companies

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2 | 2

Change to be added to the relevant section of the Summary of Product Characteristics

4.4. Special warnings and precautions for use

Used during renal replacement therapy

During the use of caspofungin in patients receiving continuous renal replacement therapy, the use of polyacrylonitrile-derived membranes (e.g. used during hemofiltration or hemodiafiltration) may lead to adsorption of the drug, potentially reducing the efficacy of caspofungin. Increasing the dose may not prevent this effect. Therefore, the use of an alternative extracorporeal membrane or other antifungal agent is recommended. The risk of treatment failure can lead to worsening of the infection and death.

Change to be added to the relevant section of the Patient Information Leaflet

2. What you need to know before you take <DRUGNAME>

Take <DRUGNAME> with CAUTION in the following conditions: Used during renal replacement therapy

If you are receiving continuous renal replacement therapy, the use of polyacrylonitrile-derived membranes (e.g. used during hemofiltration or hemodiafiltration) during the use of caspofungin may lead to adsorption of the drug and consequently decrease drug efficacy. This may cause the risk of treatment failure, worsening of the infection, and death. Increasing the dose may not prevent this effect. Your doctor may recommend the use of an alternative extracorporeal membrane or other antifungal agent.