



Summary of investigation results

Caspofungin acetate

April 20, 2017

Non-proprietary name

Caspofungin acetate

Brand name (Marketing authorization holder)

Candidas for Intravenous Drip Infusion 50 mg and 70 mg (MSD K.K.)

Indications

1. Febrile neutropenia suspected of a fungal infection
2. The following fungal infections due to *Candida* or *Aspergillus*
 - Esophageal candidiasis
 - Invasive candidiasis
 - Aspergillosis (invasive aspergillosis, chronic necrotizing pulmonary aspergillosis, pulmonary aspergilloma)

Summary of revision

“Toxic epidermal necrolysis” and “oculomucocutaneous syndrome” should be added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of toxic epidermal necrolysis or oculomucocutaneous syndrome have been reported in patients treated with caspofungin acetate both in Japan and overseas. CCDS* has been revised as well as the United States and European package inserts. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

No case associated with toxic epidermal necrolysis has been reported. One case

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associated with oculomucocutaneous syndrome has been reported (including no cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

NOTE:

*CCDS is prepared by the marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.