



Summary of investigation results

Fluconazole and Fosfluconazole

July 4, 2017

Non-proprietary name

- a. Fluconazole
- b. Fosfluconazole

Brand name (Marketing authorization holder)

- a. Diflucan Capsules 50 mg, 100 mg, Diflucan Dry Syrup 350 mg, 1400 mg, Diflucan Intravenous Solution 50 mg, 100 mg, 200 mg (Pfizer Japan Inc.), and the others
- b. Prodif Intravenous Solution 100 mg, 200 mg, 400 mg (Pfizer Japan Inc.)

Indications

See Attachment

Summary of revision

“Drug-induced hypersensitivity syndrome” should be added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

- a. Cases of drug-induced hypersensitivity syndrome have been reported in patients treated with fluconazole both in Japan and overseas, and the company core data sheet (CCDS) has been revised. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.
- b. Cases of drug-induced hypersensitivity syndrome have been reported in patients treated with fosfluconazole in Japan. Considering that fosfluconazole is a pro-drug of fluconazole and following investigation results 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

a. Fluconazole

A total of 2 cases associated with drug-induced hypersensitivity syndrome have been reported (including one case for which a causal relationship to the product could not be ruled out). No fatality has been reported.

b. Fosfluconazole

One case associated with drug-induced hypersensitivity 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.

This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Attachment

Non-proprietary name	Indications
a. Fluconazole	<p>Capsules:</p> <p>The following infections with Candida or Cryptococcus Fungemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis</p> <p>Prophylaxis of deep mycosis in hematopoietic stem cell transplant patients</p> <p>Vaginitis and vulvovaginitis due to Candida</p> <p>Dry Syrup and Injections:</p> <p>The following infections with Candida or Cryptococcus Fungemia, respiratory mycosis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis</p> <p>Prophylaxis of deep mycosis in hematopoietic stem cell transplant patients</p>
b. Fosfluconazole	<p>The following infections with Candida or Cryptococcus Fungemia, respiratory mycosis, fungal peritonitis, gastrointestinal mycosis, urinary tract mycosis, fungal meningitis</p>