



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

# Revision of Precautions

## Fluconazole and Fosfluconazole

July 4, 2017

### Non-proprietary name

- Fluconazole
- Fosfluconazole

### Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

#### Drug-induced hypersensitivity syndrome:

Initial symptoms of pyrexia and rash, followed by serious delayed symptoms of hypersensitivity accompanied by hepatic function disorder, swollen lymph nodes, increased white blood cell, eosinophilia, and appearance of atypical lymphocytes may occur. Patients should be carefully monitored. If such symptoms are observed, administration of this drug should be discontinued and appropriate measures should be taken. Symptoms are often accompanied by virus reactivation such as human herpes virus type 6 (HHV-6). Caution should be exercised against recurrence or prolongation of rash, pyrexia, and hepatic function disorder, etc. that may occur even after discontinuation of administration.

<Reference> MHLW: Manuals for Management of Individual Serious Adverse Drug Reactions: Drug induced Hypersensitivity Syndrome