



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

Voriconazole, Itraconazole, Fluconazole, Fosfluconazole

October 18, 2016

Non-proprietary name

- Voriconazole
- Itraconazole
- Fluconazole
- Fosfluconazole

Safety measure

Precautions should be revised in the package insert.

In the Careful Administration section, the following text should be added (underlined parts are revised):

Patients receiving warfarin:

In the Important Precautions section, the following text should be added (underlined parts are revised):

A marked increase in INR resulting from increased effects of warfarin has been reported in patients receiving the product concomitantly with warfarin. Whether a patient takes warfarin must be confirmed before initiating treatment with the product. In case of concomitant use with warfarin, extreme caution should be exercised during administration by taking adequate measures such as increasing the frequency of prothrombin time measurement and thrombotest.

Pharmaceuticals and Medical Devices Agency

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* Fosfluconazole is designated as a drug requiring preparation of a Drug Guide for Patients.

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