Published by Ministry of Health, Labour and Welfare



Translated by Pharmaceuticals and Medical Devices Agency



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 Miconazole

October 18, 2016

## Non-proprietary name

Miconazole

## Safety measure

Precautions should be revised in the package insert.

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

#### Patients receiving warfarin potassium:

In the Contraindications for Concomitant Use subsection of the Interactions section, the following text should be added (underlined parts are revised):

#### Warfarin potassium

\* Miconazole (gel, injection) are designated as a drug requiring preparation of a Drug Guide for Patients.

Pharmaceuticals and Medical Devices Agency Office of Safety I 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u>