



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

Gardenia fruit

Non-proprietary name

Gardenia fruit

Safety measure

Precautions should be revised in the package insert.

The Important Precautions section should be newly added and the following texts should be included (underlined parts are revised):

When using Kampo medicine (Japanese traditional medicine) containing gardenia fruit, patient's predisposition and symptoms (so-called "Sho" in Japanese in Kampo medicine), and the indication for Kampo medicine should be considered. Patients should be carefully observed and continuation of treatment should be avoided if symptoms/signs are not improved.

Long-term use of Kampo medicine containing gardenia fruit may result in mesenteric phleboscrosis accompanied by abnormal colour, oedema, erosion, ulcer, and stenosis of the colon (most reported cases occurred after more than 5 years of treatment). Periodic examinations including computed tomography and large bowel endoscopy are recommended when long-term use is needed.

When taken concomitantly with Kampo products etc., caution should be exercised regarding duplicative doses of the herbal medicines contained.

Published by
Ministry of Health, Labour and Welfare



Translated by
Pharmaceuticals and Medical Devices Agency



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The Adverse Reactions section and the Clinically Significant Adverse Reactions subsection should be newly added and the following text should be included (underlined parts are revised):

Mesenteric phlebosclerosis:

Mesenteric phlebosclerosis may occur with long-term use of Kampo medicine containing gardenia fruit. If abdominal pain, diarrhoea, constipation, abdominal distension, and other signs and symptoms repeatedly occur, or if the patient tests positive for faecal occult blood, administration should be discontinued. At the same time, examinations such as computed tomography and large bowel endoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases.

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