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*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

## Unseiin, kamikihito, keigairengyoto, gorinsan, saikoseikanto, shishihakuhito, seijobofuto, seihaito, bofutsushosan, ryutanshakanto

### Non-proprietary name

Unseiin, kamikihito, keigairengyoto, gorinsan, saikoseikanto, shishihakuhito, seijobofuto, seihaito, bofutsushosan, ryutanshakanto

### Safety measure

Precautions should be revised in the package insert.

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

Long-term use of Kampo medicine (Japanese traditional medicine) containing gardenia fruit may result in mesenteric phlebosclerosis 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.



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

Mesenteric phlebosclerosis:

Mesenteric phlebosclerosis may occur with long-term administration. 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.