



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

Inchinkoto, orengedokuto, kamishoyosan, shiniseihaito

Non-proprietary name

Inchinkoto, orengedokuto, kamishoyosan, shiniseihaito

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.