



---

*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 for ethical use

July 8, 2014

### Non-proprietary Name

Inchinkoto

### Safety measure

Precautions should be revised in the package inserts.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts 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 of this drug 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.