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.