



Summary of investigation results

Inchinkoto for ethical use

July 8, 2014

Non-proprietary Name

Inchinkoto

Brand Name (Marketing Authorization Holder)

TSUMURA Inchinkoto extract granules for ethical use (Tsumura & Co.) and the others

Indications

Inchinkoto is indicated for the relief of the following symptoms of those patients with a comparatively strong constitution having somewhat tendency to constipation, and decreased urine volume:

Jaundice, hepatic cirrhosis, nephrosis, urticaria, and stomatitis

Summary of revision

‘Mesenteric phlebosclerosis’ should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of mesenteric phlebosclerosis have been reported in patients treated with Inchinkoto in Japan. Following an investigation result based of opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan

A total of 5 mesenteric phlebosclerosis-associated cases has been reported (including 4 cases in which causality could not be ruled out). Of the 5 cases, no fatalities have been reported.