



Summary of investigation results

Inchinkoto for OTC drugs

July 8, 2014

Non-proprietary Name

Inchinkoto

Brand Name (Marketing Authorization Holder)

Kracie kampo inchinkoto extract granule (Kracie Pharma, Ltd.) and the others

Indications

Following symptoms of those patients with a moderate to strong constitution who have thirst, decreased urine volume, and constipation:

Urticarias, stomatitis, eczema/dermatitis, and itchy skin

Summary of revision

‘Mesenteric phlebosclerosis’ should be added in Consultation section.

Background of the revision and investigation results

The MHLW/PMDA concluded that revision of the package insert of Inchinkoto for ethical use was necessary. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert of Inchinkoto for OTC drugs was also necessary.

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

A mesenteric phlebosclerosis case has been reported. A causal relationship with Inchinkoto for OTC drugs was not established in the case. No fatalities has been reported.