



Summary of investigation results

Preparations containing gardenia fruit (OTC drugs) (oral dosage form)

Non-proprietary name

- a. Seihaito
- b. Bofutsushosan
- c. Shishihakuhito
- d. Kamikihito
- e. Ryutanshakanto
- f. Gorinsan
- g. Unseiin
- h. Keigairengyoto
- i. Saikoseikanto
- j. Seijobofuto
- k. Inchinkoto
- l. Orengedokuto
- m. Shiniseihaito
- n. Kamishoyosan
- o. Other kampo preparations containing gardenia fruit
- p. Herbal medicine preparations containing gardenia fruit
- q. The others

Brand name (Marketing authorization holder)

See Appendix.

Indications



See Appendix.

Summary of revision

a. to j., and o. to q.

1. “Mesenteric phlebosclerosis” should be added in the Consultation section.

a. to q

2. “Contact a physician, pharmacist, or registered distributor for a consultation when long-term use of this drug is needed.” should be added in the Consultation section.

Background of the revision and investigation results

Package inserts of prescription drugs of gardenia fruit and Kampo medicines (Japanese traditional medicines) containing gardenia fruit are to be revised. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary for OTC drugs in oral dosage form as well.

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

Mesenteric phlebosclerosis

a. to j and l to q. None

k. One* case has been reported.

a. to q. No fatal cases have been reported.

*: Causal relationship has not been evaluated.

Appendix

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No.	Non-proprietary name	Representative products		
		Brand name	MAH	Indications
a.	Seihaito	Dasmoc a	Kobayashi Pharmaceuticals Co., Ltd.	The following symptoms of those patients with moderate constitution who persistently cough with frequent sputum and difficulty clearing their throat: Coughing accompanied by frequent sputum
b.	Bofutsushosan	Tsumura Kampo Bofutsushosan Extract Granules	Tsumura and Co.,	The following symptoms of those patients with strong constitution and thick subcutaneous fat in the abdomen who tend to constipate: Palpitation/shoulder stiffness/hot flushes/swelling/constipation accompanying hypertension or obesity, empyema (sinusitis), eczema or dermatitis, rash (acnes), obesity
c.	Shishihakuhito	Uchida Shishihakuhito	Uchida Wakanyaku Ltd.	The following symptoms of those patients with moderate constitution without coldness but sometimes with itching: Eczema or dermatitis, itching, hyperemia of eyes
d.	Kamikihito	Kamikihito Extract Granules Kracie a	Kracie Pharma Ltd.	The following symptoms of those patients with moderate or weaker constitution who are tired mentally and physically, of a poor complexion, sometimes accompanied with heat sensation: Anemia, insomnia, mental anxiety, neurosis

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		Brand name	MAH	Indications
e.	Ryutanshakanto	Ryutanshakanto Extract Granules Kracie	Kracie Pharma Ltd.	The following symptoms of those patients with moderate or stronger constitution who have a heat sensation or pain in the lower abdomen: Micturition pain, feeling of residual urine, turbid urine, leucorrhea (vaginal discharge), frequent urination
f.	Gorinsan	Gorinsan Extract Fine G Kotaro	Kotaro Pharmaceuticals Co., Ltd.	The following symptoms of those patients with moderate constitution: Frequent urination, micturition pain, feeling of residual urine, turbid urine
g.	Unseiin	Tsumura Kampo Unseiin Extract Granules	Tsumura and Co.,	The following symptoms of those patients with moderate constitution and a sallow complexion in flaky skin who have hot flushes: Menstrual irregularity, dysmenorrhea, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, climacteric disturbance, neurosis, eczema or dermatitis
h.	Keigairengyoto	Tsumura Kampo Keigairengyoto Extract Granules	Tsumura and Co.,	The following symptoms of those patients with moderate or stronger constitution with dark skin who occasionally experience oily sweat on their palms or soles of the feet as well as a tension sensation at the abdominal wall: Empyema (sinusitis), chronic rhinitis, chronic tonsillitis, acne

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		Brand name	MAH	Indications
i.	Saikoseikanto	Saikoseikanto Extract fine G Kotaro	Kotaro Pharmaceuticals Co., Ltd.	The following symptoms of those patients with moderate constitution who tend to be irritable (nervousness) : Neurosis, chronic tonsillitis, eczema or dermatitis, improvement of childhood infirmity
j.	Seijobofuto	Tsumura Kampo Seijobofuto Extract Granules	Tsumura and Co.,	The following symptoms of those patients with moderate or stronger constitution and ruddy complexion who sometimes have hot flashes: Acnes, eczema or dermatitis in the head/face, red nose (rosacea),
k.	Inchinkoto	Kracie Kampo Inchinkoto Extract Granules	Kracie Pharma Ltd.	The following symptoms of those patients with moderate or stronger constitution who have thirst, decreased urine volume, and constipation: Urticaria, stomatitis, eczema or dermatitis, itchy sensation of the skin
l.	Orengedokuto	Tsumura Kampo Orengedokuto Extract Granules	Tsumura and Co.,	The following symptoms of those patients with moderate or stronger constitution who have ruddy face, a touch of hot flushes, and a tendency to irritability and restlessness: Nose bleeding, insomnia, neurosis, gastritis, alcoholic hangover, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, dizziness, palpitation, climacteric disturbance, eczema or dermatitis, itchy

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		Brand name	MAH	Indications
				sensation of the skin, stomatitis
m.	Shiniseihaito	Shiiseihaito Extract Fine G Kotaro	Kotaro Pharmaceuticals Co., Ltd.	The following symptoms of those patients with moderate constitution who have dense nasal discharge sometimes accompanied with heat sensation: Blocked nose, chronic rhinitis, and empyema (sinusitis)
n.	Kamishoyosan	Tsumura Kampo Kamishoyosan Extract Granules	Tsumura and Co.,	The following symptoms of those patients with moderate or weaker constitution having a touch of hot flushes who are easily fatigued and are apt to have stiffness shoulder, psychoneurotic symptoms including anxiety, and sometimes tendency to constipation: Oversensitivity to cold, delicate constitution, menstrual irregularity, dysmenorrhea, climacteric disturbance, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, and insomnia
o.	Other kampo preparations containing gardenia fruit	Jijinmeimokuto Extract Fine G Kotaro	Kotaro Pharmaceuticals Co., Ltd.	The following symptoms of those patients with delicate constitution: Blear eye, eye strain, eye pain
p.	Natural medicine	Actoman	Zaiseido Yakuhin	The following symptoms of those patients with allergic

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		Brand name	MAH	Indications
	preparations containing gardenia fruit		Co., Ltd.	constitution: Acne, eczema, dermatitis, urticaria, cutaneous pruritus, nose bleeding
q.	Others	Goreiouce Oral Solution	JPS Pharmaceuticals Co., Ltd.	Excessive drinking, overeating, feeling queasy (alcoholic hangover or sickness from drinking, churning of the stomach, sickness, nausea), poor appetite, stomach feeling heavy, feeling of fullness in stomach and abdomen, heartburn, feeling of something lying heavy on the stomach, weak stomach, vomiting, dyspepsia

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