Revised: February 2018 (9th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Inchinkoto Extract Granules

< Inchinkoto >

Storage
Store at room temperature in a tight container. [See the "Precaution for handling" section.]

Expiration date
Inchinkoto should be used before the expiration date indicated on the label and the package.

Approval No.	(61AM) 3684
Date of listing in the NHI reimbursement price	July 1988
Date of initial marketing in Japan	July 1988

DESCRIPTION

Composition	7.5 g of TEIKOKU Inchinkoto Extract Granules contains 1.39 g of a dried water extract of the following mixed crude drugs. JP Artemisia Capillaris Flower --- 6.0 g JP Gardenia Fruit ---------- 2.0 g JP Rhubarb ---------- 2.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
Description	Dosage form	Granules
	Color	Light brown
	Smell	Characteristic smell
	Taste	Bitter
	ID code	TEIKOKU 135

INDICATIONS

The following symptoms of those patients with thirst, decreased urine volume, and constipation:
Urticaria and stomatitis

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Inchinkoto Extract Granules three times daily before meals.
The dosage may be adjusted according to the patient's age, body weight, and symptoms.

PRECAUTIONS

1. Careful Administration (Inchinkoto should be administered with care in the following patients.)

(1) Patients with diarrhea or soft feces [These symptoms may be aggravated.]

(2) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, abdominal pain, diarrhea may occur.]

(3) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

2. Important Precautions

(1) When this product is used, the patient's "SHO" (constitution/symptoms) should be taken into account. The patient's progress should be carefully monitored, and if no improvement in symptoms/findings is observed, continuous treatment should be avoided.

(2) Long-term administration of a gardenia fruit-containing preparation (usually 5 years or longer) may cause mesenteric phlebosclerosis accompanied by discoloration, edema, erosion, ulceration, and stenosis of the colon. Periodical examinations such as CT scanning and colonoscopy would be desirable in cases of its long-term administration.

(3) When this product is coadministered with other Kampo-preparations (Japanese traditional herbal medicines), etc., attention should be paid to the duplication of the contained crude drugs. Special caution should be exercised when this product is coadministered with preparations containing Rhubarb.

(4) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

SHO : The term "SHO" refers to a particular pathological status of a patient evaluated by the Kampo diagnosis, and is patterned according to the patient's constitution, symptoms, etc. Kampo-preparations (Japanese traditional herbal medicines) should be used after confirmation that it is suitable for the identified "SHO" of the patient.

3. Adverse Reactions

This product has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

(1) Clinically significant adverse reactions

1) Hepatic dysfunction and jaundice: Hepatic dysfunction and/or jaundice with elevation of AST (GOT), ALT (GPT), Al-P and γ-GTP or other symptoms may occur. The patient should be carefully monitored for abnormal findings. Administration should be discontinued and appropriate therapeutic measures should be taken, if abnormalities are observed.

2) Mesenteric phlebosclerosis: Mesenteric phlebosclerosis may occur with long-term administration. If symptoms such as abdominal pain, diarrhea, constipation, and abdominal distension repeatedly occur, or if the patient tests positive for fecal occult blood, administration should be discontinued. At the same time, tests such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases.

(2) Other adverse reactions

	Incidence unknown
Gastrointestinal	Anorexia, Epigastric distress, Abdominal pain, Diarrhea, etc.

4. Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

5. Use during Pregnancy, Delivery or Lactation

(1) Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in this product may cause premature birth or abortion.]

(2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in breast milk and induce diarrhea in nursing infants.]

6. Pediatric Use

The safety of this product in children has not been established. [Insufficient clinical data.]

PRECAUTIONS FOR HANDLING

1.This product should not be stored in direct rays and should be stored in a cool place with, if possible, little humidity.

2.Since it is hygroscopic property, this product should not be stored in humid places after opening.

PACKAGING

Bottles of 500 g

Boxes of 2.5 g× 42 packets

Boxes of 2.5 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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