

Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Keishikashakuyakudaioto Extract Granules for Ethical Use

<keishikashakuyakudaioto>

Storage
Store in light-resistant, air-tight containers.

Approval No.	(61AM)1170
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

Expiration date
Use before the expiration date indicated on the container and the outer package.

DESCRIPTION

Composition	7.5 g of TSUMURA Keishikashakuyakudaioto extract granules contains 4.0 g of a dried extract of the following mixed crude drugs.	
	JP Peony Root	6.0 g
	JP Cinnamon Bark	4.0 g
	JP Jujube	4.0 g
	JP Glycyrrhiza	2.0 g
	JP Rhubarb	2.0 g
	JP Ginger	1.0 g
	(JP: The Japanese Pharmacopoeia)	
	Inactive ingredient	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Yellow-brown
	Smell	Characteristic smell
	Taste	Pungent and slightly astringent
	ID code	TSUMURA/134

INDICATIONS

TSUMURA Keishikashakuyakudaioto Extract Granules (hereafter TJ-134) is indicated for the relief of the following symptoms of those patients with comparatively deprived constitution having abdominal distension accompanied by stagnation of intestinal contents or abdominal pain:

1. Acute enterocolitis and large intestinal catarrh
2. Habitual constipation, fecal impaction, and tenesmus alvi

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 g/day orally in 2 or 3 divided doses before or between meals. The dosage may be adjusted according to the patient's age and body weight, and symptoms.

PRECAUTIONS

1. Careful administration (TJ-134 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, abdominal pain, diarrhea, etc. may occur.]

2. Important Precautions

- (1) When TJ-134 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) Since TJ-134 contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc., and if any abnormality is observed, administration should be discontinued.
- (3) When TJ-134 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 TJ-134 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. Drug Interactions

Precautions for coadministration (TJ-134 should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Glycyrrhiza (2) Preparations containing glycyrrhizinic acid or glycyrrhizates	Pseudoaldosteronism is likely to occur. Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".)	Since glycyrrhizinic acid has an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested.

4. Adverse Reactions

TJ-134 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) **Pseudoaldosteronism:** Pseudoaldosteronism such as hypokalemia, increased blood pressure, retention of sodium/body fluid, edema, increased body weight, etc. may occur. The patient should be carefully monitored (measurement of serum potassium level, etc.), and if any abnormality is observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

2) **Myopathy:** Myopathy may occur as a result of hypokalemia. The patient should be carefully monitored, and if any abnormality such as weakness, convulsion/paralysis of limbs, etc. are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

(2) Other adverse reactions

	Incidence unknown
Hypersensitivity <small>Note 1)</small>	Rash, Redness, Pruritus, etc.
Gastrointestinal	Anorexia, Abdominal pain, Diarrhea, etc.

Note 1) If such symptoms are observed, administration should be discontinued.

5. Use in the Elderly

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

6. Use during Pregnancy, Delivery or Lactation

(1) Use of TJ-134 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 TJ-134 may cause premature birth or abortion.]

(2) TJ-134 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-134 may be excreted in breast milk and induce diarrhea in nursing infants.]

7. Pediatric Use

The safety of TJ-134 in children has not been established. [Insufficient clinical data]

PACKAGING

Bottles of 500 g
2.5 g × 42 packets
2.5 g × 189 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan

Manufactured and Distributed by:

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