

Revised: March 2013 (6th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Otsujito Extract Granules for Ethical Use

<otsujito>

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

Approval No.	(61AM)1149
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 Otsujito extract granules contains 4.0 g of a dried extract of the following mixed crude drugs.	
		JP Japanese Angelica Root 6.0 g
		JP Bupleurum Root 5.0 g
		JP Scutellaria Root 3.0 g
		JP Glycyrrhiza 2.0 g
		JP Cimicifuga Rhizome 1.0 g
		JP Rhubarb 0.5 g
	(JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Light yellow-brown
	Smell	Characteristic smell
	Taste	Sweet
	ID code	TSUMURA/3

- (3) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]
- (4) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

2. Important Precautions

- (1) When TJ-3 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-3 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-3 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-3 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.

INDICATIONS

TSUMURA Otsujito Extract Granules (hereafter TJ-3) is indicated for the relief of the following symptoms of those patients with a moderately strong constitution without very severe symptoms or debility:

Anal fissure and hemorrhoids

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-3 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, nausea, abdominal pain, diarrhea, etc. may occur.]

3. Drug Interactions

Precautions for coadministration (TJ-3 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 glycyrrhizinates	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-3 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) **Interstitial pneumonia:** If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of TJ-3 should be discontinued, and examinations such as X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken. Besides, the patient should be advised to discontinue TJ-3 immediately and to make contact with the physician in the event of fever, cough, dyspnea, etc.
- 2) **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.
- 3) **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.
- 4) **Hepatic dysfunction and jaundice:** Hepatic dysfunction and/or jaundice with remarkable 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) Other adverse reactions

	Incidence unknown
Hypersensitivity Note 1)	Rash, Redness, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, 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-3 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-3 may cause premature birth or abortion.]
- (2) TJ-3 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-3 may be excreted in breast milk and induce diarrhea in nursing infants.]

7. Pediatric Use

The safety of TJ-3 in children has not been established. [Insufficient clinical data]

PACKAGING

- Bottles of 500 g
- 2.5 g \times 42 packets
- 2.5 g \times 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

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