Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

■84■

- Kampo-preparation-

TSUMURA Daiokanzoto Extract Granules for Ethical Use

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

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

Approval No.	(61AM)3319
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986
Date of latest reevaluation	March 1996

DESCRIPTION

Composition	7.5 g of TSUMURA Daiokanzoto extract granules (hereafter TJ-84) contains 1.5 g of a dried extract of the following mixed crude drugs. JP Rhubarb ..... 4.0 g JP Glycyrrhiza ..... 2.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredient	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Yellow-brown
	Smell	Characteristic smell
	Taste	Slightly sweet and astringent
	ID code	TSUMURA/84

INDICATIONS

TJ-84 is indicated for the relief of the following symptoms:
Constipation

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-84 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.]
   (3) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]
2. **Important Precautions**
   (1) When TJ-84 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-84 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-84 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-84 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-84 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-84 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
Gastrointestinal	Anorexia, Abdominal pain, Diarrhea, etc.

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-84 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-84 may cause premature birth or abortion.]

(2) TJ-84 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-84 may be excreted in breast milk and induce diarrhea in nursing infants.]

7. Pediatric Use

The safety of TJ-84 in children has not been established. [Insufficient clinical data]

CLINICAL STUDIES

TJ-84 showed the following result in a double-blind comparative clinical study involving patients with constipation[1].

	Efficacy rate : % (n)
TJ-84 group	86.4 (38/44)
Placebo group	44.7 (21/47)

PACKAGING

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

REFERENCES

1) Miyoshi, A. et al. Gastroenterology. 1996, 22(3), p.314.

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Consumer Information Services Center
Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan
TEL:0120-329970 FAX:03-5574-6610

Manufactured and Distributed by:

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