Revised: August 2017 (8th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Otsujito Extract Granules

< Otsujito >

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

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

Approval No.	(61AM) 3673
Date of listing in the NHI reimbursement price	July 1988
Date of initial marketing in Japan	July 1988

CONTRAINDICATIONS (Otsujito is contraindicated in the following patients.)

1. Patients with aldosteronism
2. Patients with myopathy
3. Patients with hypokalemia

[1-3: These diseases or symptoms may be aggravated.]

DESCRIPTION

Composition	9.0 g of TEIKOKU Otsujito Extract Granules contains 4.27 g of a dried water 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 ---------- 3.0 g JP Cimicifuga Rhizome ---------- 1.0 g JP Rhubarb ---------- 1.0 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	Sweet and bitter
	ID code	TEIKOKU 3

INDICATIONS

The following symptoms of those patients with discharged hard stools and a tendency to constipation:
Hemorrhoids, anal fissure and constipation

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 3.0 g of TEIKOKU Otsujito 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 (Otsujito 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) 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 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) Since this product 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 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. Drug Interactions

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

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Preparations containing Glycyrrhiza Preparations containing glycyrrhizinic acid or glycyrrhizinates Loop diuretics Furosemide Etacrynic acid Thiazide diuretics Trichlormethiazide	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 and diuretics have 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

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) **Interstitial pneumonia:** If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of this product 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 this product 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)	Rash, Redness, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausia, Abdominal pain, Diarrhea, etc.

Note) 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 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.]

7. 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 3.0 g×42 packets
Boxes of 3.0 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Product Information Unit,
Pharmaceutical Sales & Marketing Dept.
Teikoku Seiyaku Co., Ltd.
6-6 Nihonbashi-kobunacho, Chuo-Ku, Tokyo
103-0024, Japan
Tel 0120-189-567

Manufactured by:

Teikoku Kampo Seiyaku Co., Ltd.
80-11 Kitahara, Donari, Donari-cho, Awa, Tokushima
771-1506, Japan

Distributed by:

Teikoku Seiyaku Co., Ltd.
567, Sanbonmatsu, Higashikagawa, Kagawa
769-2695, Japan