Revised: May 2007 (4th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Sokeikakketsuto Extract Granules for Ethical Use

<sokeikakketsuto>

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)3271
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

DESCRIPTION

Composition	7.5 g of TSUMURA Sokeikakketsuto extract granules contains 5.0 g of a dried extract of the following mixed crude drugs. JP Peony Root ..... 2.5 g JP Rehmannia Root ..... 2.0 g JP Cnidium Rhizome ..... 2.0 g JP Atractylodes Lancea Rhizome ..... 2.0 g JP Japanese Angelica Root ..... 2.0 g JP Peach Kernel ..... 2.0 g JP Poria Sclerotium ……. 2.0 g JP Clematis Root ……..….. 1.5 g JP Notopterygium ……..... 1.5 g JP Achyranthes Root …… 1.5 g JP Citrus Unshiu Peel ……... 1.5 g JP Sinomenium Stem …… 1.5 g JP Saposhnikovia Root ……. 1.5 g JP Japanese Gentian …….. 1.5 g JP Glycyrrhiza …….. 1.0 g JP Angelica Dahurica Root ……... 1.0 g JP Ginger …….. 0.5 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Light Anhydrous Silicic Acid JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Light grayish-brown
	Smell	Characteristic smell
	Taste	Bitter and acrid
	ID code	TSUMURA/53

INDICATIONS

Sokeikakketsuto is indicated for the relief of the following symptoms:
Arthralgia, neuralgia, low back pain, and myalgia

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 (Sokeikakketsuto should be administered with care in the following patients.)

(1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea etc. may occur.]

(2) Patients with anorexia, nausea or vomiting [These 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.

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 (Sokeikakketsuto 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

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) 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, Epigastric distress, Nausea, Vomiting, 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

Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [Achyranthes Root or Peach Kernel contained in this product may cause premature birth or abortion.]

7. Pediatric Use

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

PACKAGING

Bottles of 500 g and boxes of 5 kg (500 g × 10 bottles)
2.5 g × 42 packets
2.5 g × 189 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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

Manufactured by:

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