Revised: August 2017 (8th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Keishikajutsubuto Extract Granules

< Keishikajutsubuto >

Powerful drug: Bottles of 500 g

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

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

Approval No.	(61AM) 3699
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

Composition	7.5 g of TEIKOKU Keishikajutsubuto Extract Granules contains 2.54 g of a dried water extract of the following mixed crude drugs. JP Cinnamon Bark ---------- 4.0 g JP Peony Root ---------- 4.0 g JP Jujube ---------- 4.0 g JP Ginger ---------- 1.0 g JP Glycyrrhiza ---------- 2.0 g JP Atractylodes Lancea Rhizome ----- 4.0 g JP Powdered Processed Aconite Root----- 0.5 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 18

INDICATIONS

Arthralgia and neuralgia

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Keishikajutsubuto 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 (Keishikajutsubuto should be administered with care in the following patients.)

(1) Patients with strong constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

(2) Patients with sensitivity to heat, a tendency towards hot flush and red face. [Palpitation, hot flush, numbness of the tongue, nausea, etc. may occur.]

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 Aconite Root.

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 (Keishikajutsubuto 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	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
Hypersensitivity Note)	Rash, Redness, Uriticaria, etc.
Others	Palpitation, Hot flush, Numbness of the tongue, Nausea, 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

Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [Adverse reactions due to Powdered processed aconite root contained in this product are likely to occur.]

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 2.5 g× 42 packets

Boxes of 2.5 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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