Revised: August 2017 (7th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Keishibukuryoganryo Extract Granules

< Keishibukuryoganryo >

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

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

Approval No.	(61AM) 3700
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 Keishibukuryoganryo Extract Granules contains 2.03 g of a dried water extract of the following mixed crude drugs. JP Cinnamon Bark ---------- 4.0 g JP Poria Sclerotium ---------- 4.0 g JP Moutan Bark ---------- 4.0 g JP Peach Kernel ---------- 4.0 g JP Peony Root ---------- 4.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
Description	Dosage form	Granules
	Color	Light yellowish brown
	Smell	Characteristic smell
	Taste	Sweet and bitter
	ID code	TEIKOKU 25

INDICATIONS

The following symptoms of those patients with comparatively strong constitution who sometimes have lower abdominal pain, shoulder stiffness, dull headache, dizziness, feeling of hot flushes with lower limbs being susceptible to cold, etc.:
Menstrual irregularity, abnormal menstruation, menses painful, climacteric disturbance, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, shoulder stiffness, dizziness, dull headache, contusion, chilblain, and spots

DOSAGE AND ADMINISTRATION

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

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) 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. 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

Hepatic dysfunction and jaundice: Hepatic dysfunction, with increased AST (GOT), ALT (GPT), Al-P, and γ-GTP levels, and/or jaundice 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, Pruritus, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Diarrhea, etc.

Note) If such symptoms are observed, administration should be discontinued.

4. Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

5. Use during Pregnancy, Delivery or Lactation

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

6. 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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Pharmaceutical Sales & Marketing Dept.
Teikoku Seiyaku Co., Ltd.
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