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Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Keishibukuryogankayokuinin Extract Granules for Ethical Use

<keishibukuryogankayokuinin>

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

Approval No.	(62AM)578
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

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

DESCRIPTION

Composition	7.5 g of TSUMURA Keishibukuryogankayokuinin extract granules contains 3.75 g of a dried extract of the following mixed crude drugs.	
		JP Coix Seed 10.0 g JP Cinnamon Bark 4.0 g JP Peony Root 4.0 g JP Peach Kernel 4.0 g JP Poria Sclerotium 4.0 g JP Moutan Bark 4.0 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-white
	Smell	Characteristic smell
	Taste	Slightly sweet and slightly bitter
	ID code	TSUMURA/125

INDICATIONS

Keishibukuryogankayokuinin is indicated for the relief of the following symptoms of those patients with a comparatively strong constitution who sometimes complain of lower abdominal pain, shoulder stiffness, dull headache, dizziness, cold feet with feeling of hot flush, etc.:

Menstrual irregularity, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, acne, spots, and roughness of the hands and feet

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 (Keishibukuryogankayokuinin 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

- 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.
- 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.

	Incidence unknown
Hypersensitivity Note 1)	Rash, Redness, Pruritus, etc.
Gastrointestinal	Epigastric distress, Diarrhea, etc.

Note 1) 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 and 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.]

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 and Distributed by:

Tsumura & Co.

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