Revised: May 2007 (6th version)

Standard Commodity Classification No. of Japan
875200

■25■

- Kampo-preparation-

TSUMURA Keishibukuryogan Extract Granules for Ethical Use

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)3288
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 Keishibukuryogan extract granules(hereafter TJ-25) contains 1.75 g of a dried extract of the following mixed crude drugs. JP Cinnamon Bark ..... 3.0 g JP Peony Root ..... 3.0 g JP Peach Kernel ..... 3.0 g JP Poria Sclerotium ..... 3.0 g JP Moutan Bark ..... 3.0 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 astringent
	ID code	TSUMURA/25

INDICATIONS

TJ-25 is indicated for the relief of the following symptoms of those patients with solid constitution who have ruddy face and generally solid abdomen with resistance in the lower abdomen: Inflammation in the uterus and its adnexa, endometritis, menstrual irregularity, dysmenorrhea, leukorrhea, climacteric disturbance (headache, dizziness, feeling of hot flushes, shoulder stiffness, etc.), oversensitivity to cold, peritonitis, contusion, hemorrhoid and orchitis

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 (TJ-25 **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 TJ-25 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 TJ-25 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

TJ-25 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 1)	Rash, Redness, Pruritus, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, 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 TJ-25 in pregnant women, women who may possibly be pregnant is not recommended. [Peach Kernel, Moutan Bark contained in TJ-25 may cause premature birth or abortion.]

6. Pediatric Use

The safety of TJ-25 in children has not been established. [Insufficient clinical data.]

PHARMACOLOGY

1. Actions on hormones

Oral administration of Keishibukuryogan to immature female rats decreased the plasma levels of LH, FSH and estradiol. In addition, Keishibukuryogan reduced wet uterus weight and uterine thymidine kinase activity[1].

2. Actions on the uterus

Administration of food containing Keishibukuryogan to female SHN mice reduced uterine thymidylate synthetase activity, and inhibited development of adenomyosis uteri[2].

3. Actions on climacteric symptoms

Oral administration of Keishibukuryogan to ovariectomized rats inhibited skin temperature elevation (*in vivo*) and vasodilation (*ex vivo*) induced by calcitonin gene-related peptide (CGRP) [3].

4. Action Mechanism

Keishibukuryogan shows pharmacological effects via the following actions.

Action on climacteric symptoms

Oral administration of Keishibukuryogan to ovary-removed rats suppressed the decrease in plasma CGRP concentration, therefore inhibited the upregulation of CGRP receptors in mesenteric artery[3].

PACKAGING

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

REFERENCES

1) Sakamoto, S. et al. J. Ethnopharmacol. 1988, 23, p.151.
2) Mori, T. et al. Planta Med. 1993, 59(4), p.308.
3) Noguchi, M. et al. J. Endocrinol. 2003, 176, p.359.

■ **REQUEST FOR LITERATURE SHOULD BE MADE TO:**
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