Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

■106■

- Kampo-preparation-

TSUMURA Unkeito 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)3296
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 Unkeito extract granules (hereafter TJ-106) contains 5.0 g of a dried extract of the following mixed crude drugs. JP Ophiopogon Tuber ..... 4.0 g JP Pinellia Tuber ..... 4.0 g JP Japanese Angelica Root ..... 3.0 g JP Glycyrrhiza ..... 2.0 g JP Cinnamon Bark ..... 2.0 g JP Peony Root ..... 2.0 g JP Cnidium Rhizome ..... 2.0 g JP Ginseng ..... 2.0 g JP Moutan Bark ..... 2.0 g JP Evodia Fruit ..... 1.0 g JP Ginger ..... 1.0 g JP Gelatin ..... 2.0 g (JP : The Japanese Pharmacopoeia)	
	Inactive ingredient	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Light grayish-brown
	Smell	Characteristic smell
	Taste	Slightly pungent and astringent
	ID code	TSUMURA/106

INDICATIONS

TJ-106 is indicated for the relief of the following symptoms of those patients who feel hot flushes in the limbs and who have lip dry:

Menstrual irregularity, dysmenorrhea, leukorrhea, climacteric disturbance, insomnia, neurosis, eczema, cold feeling in the lower limbs and waist, and chilblain.

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-106 should be administered with care in the following patients.)

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

(2) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]

2. Important Precautions

(1) When TJ-106 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 TJ-106 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 TJ-106 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 (TJ-106 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

TJ-106 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 1)	Rash, Redness, Pruritus, Urticaria,etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Diarrhea, etc.

Note 1) 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 TJ-106 in pregnant women, women who may possibly be pregnant is not recommended. [Moutan Bark contained in TJ-106 may cause premature birth or abortion.]

7. Pediatric Use

The safety of TJ-106 in children has not been established. [Insufficient clinical data]

PHARMACOLOGY

1. Ovulation-inducing actions

Oral administration of TJ-106 to juvenile female rats induced ovulation at 30 or 31 days of age[1].

2. Actions on the estrus cycle

TJ-106 was orally administered to rats with stress loading-related abnormalities in the estrus cycle. Observation of vaginal smears showed recovery of the estrus cycle[2].

3. Action mechanism

TJ-106 has pharmacological effects via the following action mechanisms.

Actions on hormones

(1) Oral administration of TJ-106 to juvenile female rats decreased the pituitary gland levels of LH and FSH[1].

(2) Oral administration of TJ-106 to rats inhibited a sulpiride-induced elevation of the blood prolactin level and decrease in the estradiol level[3].

(3) TJ-106 increased the medium and intracellular levels of LH and FSH in the presence of LH-RH in a rat anterior pituitary gland cell culture system, and inhibited prolactin secretion (*in vitro*)[4].

(4) In a continuous perfusion experiment on the rat hypothalamohypophyseal system, TJ-106 enhanced LH secretion during continuous hypothalamus-pituitary gland perfusion, and LH-RH secretion during continuous hypothalamus perfusion (*in vitro*)[4].

PACKAGING

Bottles of 500 g
2.5 g × 42 packets
2.5 g × 189 packets

REFERENCES

1) Koyama, T. et al. Jpn. J. Fertil. Steril. 1991, 36(3), p.621.
2) Terawaki, K. et al. J. Jpn. Assoc. Oriental Psychosom. Med. 2001, 16(1/2), p.5.
3) Fukushima, M. et al. Recent progress of KAMPO MEDICINE in obstetrics and gynecology No.1. Sindan to Chiryosha, 1984, p.85.
4) Kugu, K. et al. Jpn. J. Fertil. Steril. 1987, 32(4), p.577.

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