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Standard Commodity Classification No. of Japan
875200

■ 113 ■

- Kampo-preparation-

TSUMURA San'oshashinto Extract Granules for Ethical Use

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

Approval No.	(61AM)3283
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

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

DESCRIPTION

Composition	7.5 g of TSUMURA San'oshashinto extract granules (hereafter TJ-113) contains 1.75 g of a dried extract of the following mixed crude drugs.	
	JP Scutellaria Root 3.0 g JP Coptis Rhizome 3.0 g JP Rhubarb 3.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Carmellose Calcium JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Yellow-brown
	Smell	Characteristic smell
	Taste	Bitter
	ID code	TSUMURA/113

INDICATIONS

TJ-113 is indicated for the relief of the following symptoms of those patients with a comparatively strong constitution who have a slight feeling of hot flush and have facial hot flushes, mental instability, and are likely to have constipation:

Symptoms associated with hypertension (flushing, shoulder stiffness, tinnitus, dull headache, insomnia, and anxiety), nose bleeding, hemorrhoidal bleeding, constipation, climacteric disturbance, and automatic imbalance syndrome peculiar to women resembling climacteric disturbance

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-113 should be administered with care in the following patients.)

- (1) Patients with diarrhea, soft feces [These symptoms may be aggravated.]
- (2) Patients with an extremely weak gastrointestinal tract [Anorexia, abdominal pain, diarrhea, etc. may occur.]
- (3) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

2. Important Precautions

- (1) When TJ-113 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-113 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 TJ-113 is coadministered with preparations containing Rhubarb.
- (3) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

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-113 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) **Interstitial pneumonia:** If fever, cough, dyspnea, abnormal pulmonary sound, etc. are observed, administration of TJ-113 should be discontinued, and examinations such as X-ray or chest CT should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken.

2) **Hepatic dysfunction and jaundice:** Hepatic dysfunction and/or jaundice with remarkable elevation of AST (GOT), ALT (GPT), AI-P and γ -GTP etc. 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
Gastrointestinal	Anorexia, Abdominal pain, Diarrhea, etc.

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

(1) Use of TJ-113 in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in TJ-113 may cause premature birth or abortion.]

(2) TJ-113 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-113 may be excreted in breast milk and induce diarrhea in nursing infants.]

6. Pediatric Use

The safety of TJ-113 in children has not been established. [Insufficient clinical data.]

PHARMACOLOGY

1. Hypotensive actions

San'oshashinto inhibited inositol (1, 4, 5) triphosphate production induced by vasopressin (*in vitro*)¹⁾.

2. Actions on the central nervous system

San'oshashinto inhibited prostaglandin E₂ release induced by the calcium ionophore(A23187) in cultured C6 rat glioma cells (*in vitro*)²⁾.

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) Takemura, H. et al. KAMPO IGAKU. 2000, 24(6), p.265.
- 2) Nakahata, N. et al. J. Traditional Med. 1998, 15(2), p.116.

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