Revised: March 2013 (6th version)

Standard Commodity Classification No. of Japan
875200

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- Kampo-preparation-

TSUMURA Shimbuto 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)1142
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 Shimbuto extract granules (hereafter TJ-30) contains 2.0 g of a dried extract of the following mixed crude drugs. JP Poria Sclerotium ..... 4.0 g JP Peony Root ..... 3.0 g JP Atractylodes Lancea Rhizome ..... 3.0 g JP Ginger ..... 1.5 g JP Powdered Processed Aconite Root ….. 0.5 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Light grayish-white
	Smell	Characteristic smell
	Taste	Pungent
	ID code	TSUMURA/30

INDICATIONS

TJ-30 is indicated for the relief of the following symptoms of those patients with decreased metabolism:
Gastrointestinal disease, weak digestive system, chronic enteritis, dyspepsia, gastric atony, gastroptosis, nephrosis, peritonitis, cerebral hemorrhage, motor paralysis and anesthesia due to spinal disease, neurasthenia, hypertension, valvular diseases of heart, palpitation due to cardiac failure, hemiplegia, rheumatism, and senile pruritus

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-30 should be administered with care in the following patients.)

(1) Patients with strong constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

(2) Patients with sensitivity to heat, a tendency towards hot flush and red face. [Palpitation, hot flush, numbness of the tongue, nausea, etc. may occur.]

2. Important Precautions

(1) When TJ-30 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-30 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-30 is coadministered with preparations containing Aconite Root.

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-30 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, Urticaria, etc.
Others	Palpitation, Hot flush, Numbness of the tongue, Nausea, 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-30 in pregnant women, women who may possibly be pregnant is not recommended. [Adverse reactions due to Powdered Processed Aconite Root contained in TJ-30 are likely to occur.]

6. Pediatric Use

TJ-30 should be administered with care in children. [TJ-30 contains Powdered Processed Aconite Root.]

PACKAGING

Bottles of 500 g
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
TEL:0120-329970 FAX:03-5574-6610

Manufactured and Distributed by:

Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan