

Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Inchingoreisan Extract Granules for Ethical Use

<inchingoreisan>

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)3286
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 Inchingoreisan extract granules contains 2.75 g of a dried extract of the following mixed crude drugs.	
		JP Alisma Rhizome 6.0 g JP Atractylodes Lancea Rhizome 4.5 g JP Polyporus Sclerotium 4.5 g JP Poria Sclerotium 4.5 g JP Artemisia Capillaris Flower..... 4.0 g JP Cinnamon Bark 2.5 g (JP: The Japanese Pharmacopoeia)
Description	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
	Dosage form	Granules
	Color	Light brown
	Smell	Characteristic smell
	Taste	Slightly astringent
	ID code	TSUMURA/117

(2) When TJ-117 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.

2. Adverse Reactions

TJ-117 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.

Note 1) If such symptoms are observed, administration should be discontinued.

INDICATIONS

TSUMURA Inchingoreisan Extract Granules (hereafter TJ-117) is indicated for the relief of the following symptoms of those patients with dry throat and decreased urine volume:

Vomiting, urticaria, hangover nausea, and swelling

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. Important Precautions

(1) When TJ-117 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.

3. Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

4. Use during Pregnancy, Delivery or Lactation

The safety of TJ-117 in pregnant women has not been established. Therefore, TJ-117 should be used in pregnant women, women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

5. Pediatric Use

The safety of TJ-117 in children has not been established. [Insufficient clinical data]

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

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