

Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Choreitogoshimotsuto Extract Granules for Ethical Use

<choreitogoshimotsuto>

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

Approval No.	(61AM)1128
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 Choreitogoshimotsuto extract granules (hereafter TJ-112) contains 5.0 g of a dried extract of the following mixed crude drugs.	
	JP Alminum Silicate Hydrate with Silicon Dioxide 3.0 g JP Rehmannia Root 3.0 g JP Peony Root 3.0 g JP Cnidium Rhizome 3.0 g JP Alisma Rhizome 3.0 g JP Polyporus Sclerotium 3.0 g JP Japanese Angelica Root 3.0 g JP Poria Sclerotium 3.0 g Donkey Glue..... 3.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Grayish-brown
	Smell	Characteristic smell
	Taste	Slightly sweet
	ID code	TSUMURA/112

INDICATIONS

TJ-112 is indicated for the relief of the following symptoms of those patients who have dry skin and a constitution with an unhealthy complexion without any gastrointestinal disorder: Difficulty in micturition, micturition pain, feeling of residual urine, and frequent urination

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-112 should be administered with care in the following patients.)

- (1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]
- (2) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]

2. Important Precautions

- (1) When TJ-112 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-112 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-112 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
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, 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

The safety of TJ-112 in pregnant women has not been established. Therefore, TJ-112 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.

6. Pediatric Use

The safety of TJ-112 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

Manufactured and Distributed by:

Tsumura & Co.

2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan