

Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

# TSUMURA Shohangekabukuryoto Extract Granules for Ethical Use

&lt;shohangekabukuryoto&gt;

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)1123
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 Shohangekabukuryoto extract granules contains 2.25 g of a dried extract of the following mixed crude drugs.	
	JP Pinellia Tuber ..... 6.0 g JP Poria Sclerotium ..... 5.0 g JP Ginger ..... 1.5 g (JP: The Japanese Pharmacopoeia)	
Description	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
	Dosage form	Granules
	Color	Light grayish-white
	Smell	Characteristic smell
	Taste	Pungent
ID code	TSUMURA/21	

(2) When TJ-21 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. Use in the Elderly

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

### 3. Use during Pregnancy, Delivery or Lactation

The safety of TJ-21 in pregnant women has not been established. Therefore, TJ-21 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.

### 4. Pediatric Use

The safety of TJ-21 in children has not been established. [Insufficient clinical data]

## INDICATIONS

TSUMURA Shohangekabukuryoto Extract Granules (hereafter TJ-21) is indicated for the relief of the following symptoms of those patients with a moderately strong constitution:

Hyperemesis gravidarum (morning sickness) and vomiting associated with other diseases (acute gastroenteritis, exudative pleurisy, wet beriberi, and empyema)

## 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-21 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.

## 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.

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