Revised: May 2007 (4th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Shimotsuto Extract Granules for Ethical Use

<shimotsuto>

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)1167
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 Shimotsuto extract granules contains 2.75 g of a dried extract of the following mixed crude drugs. JP Rehmannia Root ..... 3.0 g JP Peony Root …… 3.0 g JP Cnidium Rhizome ..... 3.0 g JP Japanese Angelica Root ..... 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	Characteristic with slightly sweet tinge
	ID code	TSUMURA/71

INDICATIONS

Shimotsuto is indicated for the relief of the following symptoms of those patients with dry skin and a sallow complexion without gastrointestinal disorder:
Recovery from fatigue after childbearing or abortion, menstrual irregularity, oversensitivity to cold, chilblain, spots, 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 (Shimotsuto 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 this product 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 this product 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

This product 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 this product in pregnant women has not been established. Therefore, the product 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 this product in children has not been established. [Insufficient clinical data.]

PACKAGING

Bottles of 500 g and boxes of 5 kg (500 g × 10 bottles)
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