Revised: August 2017 (6th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Shimotsuto Extract Granules

< Shimotsuto >

Storage
Store at room temperature in a tight container. [See the “Precaution for handling” section.]

Expiration date
Shimotsuto should be used before the expiration date indicated on the label and the package.

Approval No.	(61AM) 3747
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

Composition	7.5 g of TEIKOKU Shimotsuto Extract Granules contains 3.03 g of a dried water extract of the following mixed crude drugs. JP Japanese Angelica Root ------ 3.0 g JP Peony Root ---------- 3.0 g JP Cnidium Rhizome ---------- 3.0 g JP Rehmannia Root ---------- 3.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
Description	Dosage form	Granules
	Color	Light brown
	Smell	Slightly characteristic smell
	Taste	Sweet
	ID code	TEIKOKU 71

INDICATIONS

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

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Shimotsuto Extract Granules three times daily before meals.
The dosage may be adjusted according to the patient’s age, 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.

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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.]

PRECAUTIONS FOR HANDLING

1.This product should not be stored in direct rays and should be stored in a cool place with, if possible, little humidity.
2.Since it is hygroscopic property, this product should not be stored in humid places after opening.

PACKAGING

Bottles of 500 g
Boxes of 2.5 g× 42 packets
Boxes of 2.5 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Product Information Unit,
Pharmaceutical Sales & Marketing Dept.
Teikoku Seiyaku Co., Ltd.
6-6 Nihonbashi-kobunacho, Chuo-Ku, Tokyo
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Manufactured by:

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Distributed by:

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