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Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

# TEIKOKU Tokishakuyakusan Extract Granules

&lt; Tokishakuyakusan &gt;

<b>Storage</b>
Store at room temperature in a tight container. [See the "Precaution for handling" section.]

Approval No.	(61AM) 3704
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

<b>Expiration date</b>
Tokishakuyakusan should be used before the expiration date indicated on the label and the package.

## DESCRIPTION

Composition	7.5 g of TEIKOKU Tokishakuyakusan Extract Granules contains 3.20 g of a dried water extract of the following mixed crude drugs.	
		JP Japanese Angelica Root ----- 3.0 g
		JP Cnidium Rhizome ----- 3.0 g
		JP Peony Root ----- 4.0 g
		JP Poria Sclerotium ----- 4.0 g
		JP Atractylodes Rhizome ----- 4.0 g
		JP Alisma Rhizome ----- 4.0 g
	(JP: The Japanese Pharmacopoeia)	
Inactive ingredients	JP Lactose Hydrate	
	JP Microcrystalline Cellulose JP Magnesium Stearate	
Description	Dosage form	Granules
	Color	Light brown
	Smell	Characteristic smell
	Taste	Slightly sweet and stayed bitter
	ID code	TEIKOKU 23

## INDICATIONS

The following symptoms of those patients with comparatively weak constitution, slight oversensitivity to cold, and slight anemia who are easily fatigued and sometimes have lower abdominal pain, dull headache, dizziness, shoulder stiffness, buzzing in the ears, palpitation, etc.:

Menstrual irregularity, abnormal menstruation, menses painful, climacteric disturbance, disorders fatigue before/after childbearing or abortion (anemia, fatigue and malaise, dizziness, edema), dizziness, dull headache, shoulder stiffness, low back pain, cold feeling in the lower limbs and waist, chilblain, edema, and spots

## DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Tokishakuyakusan 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 (Tokishakuyakusan should be administered with care in the following patients.)

- (1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, abdominal pain, 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.

	<b>Incidence unknown</b>
<b>Hypersensitivity</b> <sup>Note)</sup>	Rash, Pruritus, etc.
<b>Hepatic</b>	Abnormality of hepatic function [Increased AST (GOT) and ALT (GPT) , etc. levels]
<b>Gastrointestinal</b>	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, etc.

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

**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:**

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**Distributed by:**

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