

Revised: February 2018 (9th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Kamishoyosan Extract Granules

< Kamishoyosan >

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

Approval No.	(61AM) 3654
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

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

DESCRIPTION

Composition	9.0 g of TEIKOKU Kamishoyosan Extract Granules contains 4.41 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 Atractylodes Rhizome ----- 3.0 g	
	JP Poria Sclerotium ----- 3.0 g	
	JP Bupleurum Root ----- 3.0 g	
	JP Moutan Bark ----- 2.0 g	
	JP Gardenia Fruit ----- 2.0 g	
	JP Glycyrrhiza ----- 2.0 g	
	JP Ginger ----- 1.0 g	
JP Mentha Herb ----- 1.0 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 bitter
	ID code	TEIKOKU 24

INDICATIONS

The following symptoms of those women with delicate constitution who are easily fatigued and are apt to have stiffness shoulder, psychoneurotic symptoms including anxiety, and sometimes tendency to constipation:

Oversensitivity to cold, delicate constitution, menstrual irregularity, dysmenorrhea, climacteric disturbance and automatic imbalance syndrome peculiar to women resembling climacteric disturbance

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 3.0 g of TEIKOKU Kamishoyosan 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 (Kamishoyosan 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) Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc., and if any abnormality is observed, administration should be discontinued.
- (3) Long-term administration of a gardenia fruit-containing preparation (usually 5 years or longer) may cause mesenteric phlebosclerosis accompanied by discoloration, edema, erosion, ulceration, and stenosis of the colon. Periodical examinations such as CT scanning and colonoscopy would be desirable in cases of its long-term administration.

(4) 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. Drug Interactions

Precautions for coadministration (Kamishoyosan should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Preparations containing Glycyrrhiza	Pseudoaldosteronism is likely to occur. Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".)	Since glycyrrhizinic acid has an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested.
Preparations containing glycyrrhizinic acid or glycyrrhizinates		

4. 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.

(1) Clinically significant adverse reactions

1) Pseudoaldosteronism: Pseudoaldosteronism such as hypokalemia, increased blood pressure, retention of sodium/body fluid, edema, increased body weight, etc. may occur. The patient should be carefully monitored (measurement of serum potassium level, etc.), and if any abnormality is observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

2) Myopathy: Myopathy may occur as a result of hypokalemia. The patient should be carefully monitored, and if any abnormality such as weakness, convulsion/paralysis of limbs, etc. are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

3) Hepatic dysfunction and jaundice: Hepatic dysfunction and/or jaundice with remarkable elevation of AST (GOT), ALT (GPT), Al-P and γ -GTP etc. may occur. The patient should be carefully monitored for abnormal findings. Administration should be discontinued and appropriate therapeutic measures should be taken, if abnormalities are observed.

4) Mesenteric phlebosclerosis: Mesenteric phlebosclerosis may occur with long-term administration. If symptoms such as abdominal pain, diarrhea, constipation, and abdominal distension repeatedly occur, or if the patient tests positive for fecal occult blood, administration should be discontinued. At the same time, tests such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases.

(2) Other adverse reactions

	Incidence unknown
Hypersensitivity ^{Note)}	Rash, Redness, Pruritus, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, etc.

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

5. Use in the Elderly

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

6. Use during Pregnancy, Delivery or Lactation

Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [Moutan Bark contained in this product may cause premature birth or abortion.]

7. 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 3.0 g× 42 packets
- Boxes of 3.0 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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