Revised: August 2017 (12th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Shakuyakukanzoto Extract Granules

< Shakuyakukanzoto >

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

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

Approval No.	(61AM) 3672
Date of listing in the NHI reimbursement price	July 1988
Date of initial marketing in Japan	July 1988
Date of latest reevaluation	April 2014

CONTRAINDICATIONS (Shakuyakukanzoto is contraindicated in the following patients.)

1. Patients with aldosteronism
2. Patients with myopathy
3. Patients with hypokalemia

[1-3: These diseases or symptoms may be aggravated.]

DESCRIPTION

Composition	7.5 g of TEIKOKU Shakuyakukanzoto Extract Granules contains 2.65 g of a dried water extract of the following mixed crude drugs. JP Peony Root ---------- 6.0 g JP Glycyrrhiza ---------- 6.0 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	Sweet
	ID code	TEIKOKU 68

INDICATIONS

Pain accompanied by sudden muscle spasms, myalgia or arthralgia, gastric pain, and abdominal pain

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Shakuyakukanzoto Extract Granules three times daily before meals.

The dosage may be adjusted according to the patient’s age, body weight, and symptoms.

<Precaution>

The duration of administration of this product should be limited to the minimum period required for the treatment of the patient's condition.

PRECAUTIONS

1. Careful Administration (Shakuyakukanzoto should be administered with care in the following patients.)

Elderly patients (Refer to the section “Use in the Elderly”)

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) 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 (Shakuyakukanzoto should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Preparations containing Glycyrrhiza Preparations containing glycyrrhizinic acid or glycyrrhizinates Loop diuretics Furosemide Etacrynic acid Thiazide diuretics Trichlormethiazide	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 and diuretics have an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested.

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) **Interstitial pneumonia:** If cough, dyspnea, fever, abnormal pulmonary sound, etc. are observed, administration of this product should be discontinued, and examinations such as X-ray or chest CT should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken.

2) **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.

3) **Congestive heart failure, ventricular fibrillation, ventricular tachycardia (including Torsades de Pointes):** The possibility that congestive heart failure, ventricular fibrillation, ventricular tachycardia (including Torsades de Pointes) may occur cannot be ruled out, and the patient should be carefully monitored (measurement of serum potassium levels, etc.). If any abnormal findings such as palpitations, breathlessness, malaise, dizziness, syncope, etc. are observed, administration of the drug should be discontinued and appropriate therapeutic measures taken.

4) **Myopathy:** As a result of hypokalemia, myopathy/rhabdomyolysis may occur. If weakness, muscle weakness, myalgia, convulsion/paralysis of limbs, increased CK (CPK), increased blood/urinary myoglobin are observed, administration should be discontinued and appropriate measures such as an administration of a potassium preparation taken.

5) **Hepatic dysfunction and jaundice:** Hepatic dysfunction and/or jaundice with remarkable elevation of AST (GOT), ALT (GPT), Al-P and γ-GTP or other symptoms 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.

(2) Other adverse reactions

	Incidence unknown
Hypersensitivity Note)	Rash, Redness, Pruritus, etc.
Gastrointestinal	Nausea, Vomiting, 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

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.

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

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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