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Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

# TEIKOKU Saikokeishito Extract Granules

&lt; Saikokeishito &gt;

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

Approval No.	(61AM) 3670
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

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

## DESCRIPTION

Composition	9.0 g of TEIKOKU Saikokeishito Extract Granules contains 4.42 g of a dried water extract of the following mixed crude drugs.	
		JP Bupleurum Root ----- 5.0 g JP Pinellia Tuber ----- 4.0 g JP Cinnamon Bark ----- 2.5 g JP Peony Root ----- 2.5 g JP Scutellaria Root ----- 2.0 g JP Ginseng ----- 2.0 g JP Jujube ----- 2.0 g JP Glycyrrhiza ----- 1.5 g JP Ginger ----- 1.0 g (JP: The Japanese Pharmacopoeia)
Description	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
	Dosage form	Granules
	Color	Light brown
	Smell	Slightly characteristic smell
	Taste	Sweet and bitter
	ID code	TEIKOKU 10

## INDICATIONS

Gastroenteritis with abdominal pain, common cold with slight fever, rigor, headache, nausea, etc., and symptoms in the latter stage of common cold

## DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 3.0 g of TEIKOKU Saikokeishito Extract Granules three times daily before meals.

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

## PRECAUTIONS

### 1. 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.

### 2. Drug Interactions

**Precautions for coadministration (Saikokeishito 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 glycyrrhizines		

### 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.

#### (1) Clinically significant adverse reactions

- 1) **Interstitial pneumonia:** If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of this product should be discontinued, and examinations such as X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken. Besides, the patient should be advised to discontinue this product immediately and to make contact with the physician in the event of fever, cough, dyspnea, etc.
- 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) **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.
- 4) **Hepatic dysfunction and jaundice:** Hepatic dysfunction and/or jaundice with elevation of AST (GOT), ALT (GPT), Al-P and  $\gamma$ -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
<b>Hypersensitivity</b> <sup>Note 1)</sup>	Rash, Redness, Pruritus, Urticaria, etc.
<b>Gastrointestinal</b>	Diarrhea, Constipation, Dyspepsia, etc.
<b>Urinary</b> <sup>Note 2)</sup>	Pollakiuria, Micturition pain, Hematuria, Feeling of residual urine, Cystitis, etc.

Note1) If such symptoms are observed, administration should be discontinued.

Note2) Since these symptoms may occur. The patient should be carefully monitored, and if abnormalities are observed, administration of the drug should be discontinued and appropriate therapeutic measures taken.

### 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.]

### 7. Other Precautions

Adverse reaction of interstitial pneumonia has been reported frequently with a similar prescription "Shosaikoto" in the case of combined use with interferon- $\alpha$ .

### 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  $\times$  42 packets
- Boxes of 3.0 g  $\times$  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  
103-0024, Japan  
Tel 0120-189-567

### Manufactured by:

Teikoku Kampo Seiyaku Co., Ltd.  
80-11 Kitahara, Donari, Donari-cho, Awa, Tokushima  
771-1506, Japan

### Distributed by:

Teikoku Seiyaku Co., Ltd.  
567, Sanbonmatsu, Higashikagawa, Kagawa  
769-2695, Japan