

Revised: July 2012 (5th version)

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| Standard Commodity Classification No. of Japan |
| 875200   |

-Kampo-preparation-

## SANWA Saikokeishito Extract Fine Granules

<saikokeishito>  
S-24

This product is easy to take, fine granules made from the extract of "saikokeishito" listed in "SHOKANRON""KINKIYORYAKU".

### Storage. Precautions for handling

Since this product is hygroscopic property, keep a container tightly closed in a cool place away from direct rays after use.

### Expiration date

Use before the expiration date indicated on the label or the package.

|  |               |
|--|---------------|
| Approval No.                                   | (61AM)3603    |
| Date of listing in the NHI reimbursement price | October 1986  |
| Date of initial marketing in Japan             | November 1986 |

## DESCRIPTION

### Composition

7.5g/day of this product contains 4.3g of a dried JP Saikokeishito extract of the following mixed crude drugs.

|                          |      |
|--------------------------|------|
| JP Bupleurum Root.....   | 5.0g |
| JP Pinellia Tuber.....   | 4.0g |
| JP Cinnamon Bark.....    | 2.5g |
| JP Peony Root.....       | 2.5g |
| JP Scutellaria Root..... | 2.0g |
| JP Ginseng.....          | 2.0g |
| JP Jujube.....           | 2.0g |
| JP Glycyrrhiza.....      | 1.5g |
| JP Ginger.....           | 1.0g |

(JP: The Japanese Pharmacopoeia)

It also contains Lactose Hydrate, Corn Starch, Microcrystalline Cellulose, Partly Pregelatinized Starch, Light Anhydrous Silicic Acid as inactive ingredients.

### Product Description

This product is fine granules, brown color, it has characteristic smell, and it tastes sweet and a little pungent.

ID code: S-24

## INDICATIONS

The following symptoms of those patients with spontaneous sweating who have slight fever, rigor, pressure in the chest or flank, headache, joint pain, anorexia, diarrhea and nausea, etc.:

Common cold, stomachache, abdominal pain, neuralgia, cholecystitis, and hyperchylia

## DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5g/day orally in 3 divided doses before or between meals. The dosage may be adjusted according to the patient's age 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   |
|---|---|--|
| (1) Preparations containing Glycyrrhiza                             | Pseudoaldosteronism is likely to occur.   | 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. |
| (2) Preparations containing glycyrrhizinic acid or glycyrrhizinates | Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".) |  |

### 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>Note1)</sup> | Rash, Redness, Pruritus, Urticaria, etc.  |
| <b>Gastrointestinal</b>                   | Diarrhea, Constipation, Dyspepsia, etc.   |
| <b>Urinary</b> <sup>Note2)</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- $\alpha$ .

## PACKAGING

Bottles of 500g  
2.5g x 300 packets

## Manufactured and Distributed by:

Sanwa Shoyaku Co., Ltd.  
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