Sanwa Shoyaku Co., Ltd.

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Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

SANWA Shosaikoto Extract Fine Granules

<shosaikoto>

S-11

This product is easy to take, fine granules made from the extract of "shosaikoto" 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)3610
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	November 1986
Date of latest reevaluation	March 1995
Date of latest reevaluation	April 2014

WARNINGS

1.Treatment with this product may cause interstitial pneumonia which may result in serious outcomes such as death unless appropriate measures are taken in the early phase. The patient should be carefully monitored, and if fever, cough, dyspnea, abnormal pulmonary sound(fine crackle), X-ray abnormalities, etc. are observed, administration of this product should be discontinued immediately.

2.The patient should be advised to discontinue this product and to contact the physician in the event of fever, cough, dyspnea, etc.

(Refer to the section "Clinically Significant adverse reactions".)

CONTRAINDICATIONS (Shosaikoto is contraindicated in the following patients.)

1. Patients receiving treatment with interferon preparations (Refer to the section "Drug Interactions".)
2. Patients with liver cirrhosis or hepatoma [Interstitial pneumonia may occur and cause serious outcomes such as death.]
3. Patients with liver dysfunction in chronic hepatitis with a platelet count of 100,000/mm^3 or below [Liver cirrhosis is suspected.]

DESCRIPTION

Composition

7.5g/day of this product contains 4.6g of a dried JP Shosaikoto extract of the following mixed crude drugs.

JP Bupleurum Root……...6.0g
JP Pinellia Tuber……... 5.0g
JP Scutellaria Root……3.0g
JP Jujube……... 3.0g
JP Ginseng…… 3.0g
JP Glycyrrhiza……...2.0g
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, yellow-brown color, it has characteristic smell, and it tastes sweet and a little pungent.

ID code: S-11

INDICATIONS

1.The following symptoms of those patients with moderately strong constitution, right upper abdominal tenderness accompanied by fullness and discomfort, coated tongue, oral cavity discomfort, anorexia, and/or those with slight fever and nausea:
Various acute febrile diseases, pneumonia, bronchitis, bronchial asthma, common cold, lymphadenitis, chronic gastrointestinal disorder, and insufficient postpartum recovery

2.Improvement of liver dysfunction in chronic hepatitis

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

(1) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]
(2) Patients with liver dysfunction in chronic hepatitis with a platelet count of 150,000/mm^3 or below [The disease may have progressed to cirrhosis.]

2. Important Precautions

(1) During treatment with Shosaikoto for liver dysfunction in chronic hepatitis, attention should be paid to possible change in the platelet count, and if a decreased platelet count is observed, administration should be discontinued.
(2) 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.
(3) 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.
(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

(1) Contraindications for coadministration (Shosaikoto should not be coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Interferon preparations Interferon-α Interferon-β	Interstitial pneumonia may occur. (Refer to the section "Clinically significant adverse reactions".)	The mechanism is not known.

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

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1)Preparations containing Glycyrrhiza (2)Preparations containing glycyrrhizinic acid or glycyrrhizinates (3)Loop diuretics Furosemide Etacrynic acid (4)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 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: 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.

4) 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 Note1)	Rash, Pruritus, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, Constipation, etc.
Urinary Note2)	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.

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.]

PACKAGING

Bottles of 500g
2.5g x 300 packets

Manufactured and Distributed by:

Sanwa Shoyaku Co., Ltd.
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