Sanwa Shoyaku Co., Ltd.

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Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

SANWA Otsujito Extract Fine Granules

<otsujito>

S-23

This product is easy to take, fine granules made from the extract of "otsujito" which was produced by Dr.Nanyo HARA.

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)3612
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 3.6g of a dried JP Otsujito extract of the following mixed crude drugs.

JP Rhubarb……..... 1.0g
JP Bupleurum Root…….. 5.0g
JP Cimicifuga Rhizome…… 1.5g
JP Glycyrrhiza……...2.0g
JP Scutellaria Root……3.0g
JP Japanese Angelica Root…….. 6.0g
(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 bitter and a little sweet.
ID code: S-23

INDICATIONS

The following symptoms of those patients with a tendency to constipation, anal pain and a little hemorrhage occasionally:
Hemorrhoids, anal prolapse, anal hemorrhage, and pruritus vulvae

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 (Otsujito should be administered with care in the following patients.)

(1) Patients with diarrhea or soft feces [These symptoms may be aggravated.]
(2) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, abdominal pain, diarrhea, etc. may occur.]
(3) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]
(4) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the 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) 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. Special caution should be exercised when this product is coadministered with preparations containing Rhubarb.
(4) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

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 (Otsujito 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	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.

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: 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 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
HypersensitivityNote1)	Rash, Redness, Pruritus, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Abdominal pain, Diarrhea, etc.

Note1) 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

(1) Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in this product may cause premature birth or abortion.]

(2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in breast milk and induce diarrhea in nursing infants.]

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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