Sanwa Shoyaku Co., Ltd.

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Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

SANWA Keishibukuryoganryo Extract Fine Granules

<keishibukuryoganryo>

S-27

This product is easy to take, fine granules made from the extract of "keishibukuryogan" listed in "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)3601
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

Composition

4.5g/day of this product contains 2.6g of a dried JP Keishibukuryogan extract of the following mixed crude drugs.

JP Cinnamon Bark…….. 4.0g
JP Poria Sclerotium…… 4.0g
JP Moutan Bark…….. 4.0g
JP Peach Kernel…….. 4.0g
JP Peony Root……. 4.0g
(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 bitter and a little pungent.
ID code: S-27

INDICATIONS

The following symptoms of those patients with feeling of hot flushes and being congested easily who have headache, shoulder stiffness, dizziness, palpitation, oversensitivity to cold, tenderness in the lower abdomen:

Dysmenorrhea, endometritis, myometritis, ovaritis, perimetritis, menorrhagia, hemorrhoidal bleeding, eczema, urticaria, acne, spots, dermatitis, chilblain, contusion, and subcutaneous bleeding

DOSAGE AND ADMINISTRATION

The usual adult dose is 4.5g/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 (Keishibukuryoganryo should be administered with care in the following patients.)

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) 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. 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

Hepatic dysfunction and jaundice : Hepatic dysfunction with increased AST(GOT), ALT(GPT), Al-P and γ-GTP levels, and/or jaundice 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, Diarrhea, etc.

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

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

Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [Peach Kernel, Moutan Bark contained in this product may cause premature birth or abortion.]

6. Pediatric Use

The safety of this product in children has not been established. [Insufficient clinical data.]

PACKAGING

Bottles of 500g
1.5g x 300 packets

Manufactured and Distributed by:

Sanwa Shoyaku Co., Ltd.
6-1, Hiraide-Kogyo-Danchi, Utsunomiya-city, Tochigi, 321-0905, Japan