Sanwa Shoyaku Co., Ltd.

Revised: April 2014 (7th version)

Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

SANWA Orengedokuto Extract Fine Granules

<orengedokuto>

S-15

This product is easy to take, fine granules made from the extract of "orengedokuto" listed in "GEDAIHIYOHO".

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)3604
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	November 1986
Date of latest reevaluation	April 2014

DESCRIPTION

Composition

4.5g/day of this product contains 1.7 g of a dried JP Orengedokuto extract of the following mixed crude drugs.

JP Coptis Rhizome……1.5g
JP Scutellaria Root……3.0g
JP Phellodendron Bark……. 1.5g
JP Gardenia Fruit…….. 2.0g
(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.
ID code: S-15

INDICATIONS

The following symptoms of those patients who have ruddy face with comparatively strong constitution, a touch of hot flushes, and a tendency to irritability:

Nose bleeding, hypertension, insomnia, neurosis, gastritis, alcoholic hangover, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, dizziness, palpitation, eczema or dermatitis and pruritus cutaneous

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 (Orengedokuto 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

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) 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.

3) Mesenteric phlebosclerosis: Mesenteric phlebosclerosis may occur with long-term administration. If symptoms such as abdominal pain, diarrhea, constipation, and abdominal distension repeatedly occur, or if the patient tests positive for fecal occult blood, administration should be discontinued. At the same time, tests such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases.

(2) Other adverse reactions

	Incidence unknown
Hypersensitivity[Note1)]	Rash, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, 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

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.]

PACKAGING

Bottles of 500g
1.5g x 300 packets

Manufactured and Distributed by:

Sanwa Shoyaku Co., Ltd.
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