Sanwa Shoyaku Co., Ltd.

Revised: August 2015 (4th version)

Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

SANWA Daisaikoto Extract Fine Granules

<daisaikoto>

S-31

This product is easy to take, fine granules made from the extract of "daisaikoto" 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)3624
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	November 1986

DESCRIPTION

Composition

9g/day of this product contains 5.8g of a dried JP Daisaikoto extract of the following mixed crude drugs.

JP Bupleurum Root……...6.0g
JP Pinellia Tuber……... 4.0g
JP Scutellaria Root……3.0g
JP Peony Root……...3.0g
JP Jujube……... 3.0g
JP Immature Orange…… 2.0g
JP Ginger……...2.0g
JP Rhubarb…… 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 bitter and a little pungent.
ID code: S-31

INDICATIONS

The following symptoms of those patients who have pressure or pain in the chest or flank, epigastric tenderness and discomfort, and constipation. Or those patients with diarrhea, tinnitus, anorexia and fatigue, etc.:

Cholecystitis, cholelithiasis, jaundice, gastrointestinal catarrh, arteriosclerosis, hypertension, cerebral hemorrhage, hemiplegia, obesity, asthma, neurasthenia, insomnia, chronic constipation, hemorrhoids, and intercostal neuralgia

DOSAGE AND ADMINISTRATION

The usual adult dose is 9g/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 (Daisaikoto 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, abdominal pain, diarrhea, etc. may occur.]
(3) 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. Special caution should be exercised when this product is coadministered with preparations containing Rhubarb.
(3) 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. 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 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
Gastrointestinal	Anorexia, Abdominal pain, Diarrhea, etc.

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

(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.]

6. Pediatric Use

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

PACKAGING

Bottles of 500g
3.0g x 300 packets

Manufactured and Distributed by:

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