

Revised: April 2013 (4th version)

Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

SANWA Tokishakuyakusanryo Extract Fine Granules

<tokishakuyakusanryo>

S-22

This product is easy to take, fine granules made from the extract of "tokishakuyakusan" 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)3618
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 4.8g of a dried JP Tokishakuyakusan extract of the following mixed crude drugs.

JP Japanese Angelica Root.....	3.0g
JP Cnidium Rhizome.....	3.0g
JP Peony Root.....	4.0g
JP Poria Sclerotium.....	4.0g
JP Atractylodes Rhizome.....	4.0g
JP Alisma Rhizome.....	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.

ID code: S-22

INDICATIONS

The following symptoms of those patients with anemia, oversensitivity to cold, a bad complexion, unidentified complaints such as dull headache, dizziness, shoulder stiffness, palpitation, cold feeling in the lower limbs and waist, increased urinary frequency and decreased urine volume, lower abdominal pain:

Anemia, oversensitivity to cold, climacteric disturbance, infertility, habitual abortion, nephropathy of pregnancy, nephrosis, menstrual irregularity, endometritis, abnormal blood pressure, anal prolapse, and acne vulgaris

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

- (1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc. may occur.]
- (2) Patients with anorexia, nausea or vomiting [These 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.

	Incidence unknown
Hypersensitivity ^{Note1)}	Rash, Pruritus, etc.
Hepatic	Abnormality of hepatic function [increased AST(GOT), ALT(GPT) levels, 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
2.5g x 300 packets

Manufactured and Distributed by:

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