

Revised: February 2016 (4th version)

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| Standard Commodity Classification No. of Japan |
| 875200 |

-Kampo-preparation-

Powerful drug **SANWA Tokishakuyakusankabushi Extract Fine Granules**

<tokishakuyakusankabushi>
S-29

This product is easy to take, fine granules made from the extract of "tokishakuyakusankabushi" listed in "RUIJUHOKOGI".
The extract of "tokishakuyakusankabushi" is a product which added Aconite Root to "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.

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| Approval No. | (61AM)3613 |
| 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 5.9g of a dried Tokishakuyakusankabushi extract of the following mixed crude drugs.

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|--------------------------------|------|
| JP Japanese Angelica Root..... | 3.0g |
| JP Cnidium Rhizome..... | 3.0g |
| JP Peony Root..... | 6.0g |
| JP Poria Sclerotium..... | 4.5g |
| JP Atractylodes Rhizome..... | 4.5g |
| JP Alisma Rhizome..... | 3.5g |
| JP Processed Aconite Root..... | 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, brown color, it has characteristic smell, and it tastes bitter.

ID code: S-29

INDICATIONS

The following symptoms of those patients who have a bad complexion, anemia, getting cold easily in the lower limbs and waist, headache, dull headache, increased urinary frequency, occasional dizziness, shoulder stiffness, tinnitus and palpitation:

Oversensitivity to cold in women, menorrhagia, neuralgia, chronic nephritis, climacteric disturbance, disorders during pregnancy (edema, prevention of habitual abortion, hemorrhoids, abdominal pain), and insufficient postpartum recovery

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

- (1) Patients with strong constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]
- (2) Patients with sensitivity to heat, a tendency towards hot flush and red face. [Palpitation, hot flush, numbness of the tongue, nausea, etc. may occur.]
- (3) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc. may occur.]
- (4) 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. Special caution should be exercised when this product is coadministered with preparations containing Aconite Root.
- 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 |
|-------------------------|---|
| Gastrointestinal | Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, etc. |
| Others | Palpitation, Hot flush, Numbness of the tongue, 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

Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [Adverse reactions due to Processed Aconite Root contained in this product are likely to occur.]

6. Pediatric Use

This product should be administered with care in children.

[This product contains Processed Aconite Root.]

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