

-Kampo product-

SG-23 OHSUGI Tokishakuyakusanryo
Extract Granules G

SG-23 T OHSUGI Tokishakuyakusanryo
Extract T Tablets
(Tokishakuyakusan)

Storage : Store at room temperature

Shelf Life : 3 years

| | Approval No. | Date of Initial Marketing in Japan |
|------------|------------------|------------------------------------|
| Granules G | 16100AMZ04811000 | October 1987 |
| T Tablets | 16100AMZ04786000 | October 1987 |

3. COMPOSITION AND PRODUCT DESCRIPTION**3.1 Composition**

| Brand name | OHSUGI Tokishakuyakusanryo Extract Granules G | OHSUGI Tokishakuyakusanryo Extract T Tablets |
|-------------------|--|--|
| Active ingredient | The daily dose of this product, 7.5 g, contains 4.2 g of the dried extract (Tokishakuyakusanryo extract) from the following mixed crude drugs. | The daily dose of this product, 18 tablets, contains 4.2 g of the dried extract (Tokishakuyakusanryo extract) from the following mixed crude drugs. |
| | JP Japanese Angelica Root | 3 g |
| | JP Cnidium Rhizome | 3 g |
| | JP Peony Root | 4 g |
| | JP Poria Sclerotium | 4 g |
| | JP Atractylodes Rhizome | 4 g |
| | JP Alisma Tuber | 4 g |
| | JP : Japanese Pharmacopoeia | |
| Excipients | Lactose Hydrate, Corn Starch and Magnesium Stearate | Microcrystalline Cellulose, Magnesium Aluminometasilicate, Carmellose Calcium, Magnesium Stearate, Hypromellose, Titanium Oxide, FD&C Yellow No.6 [Sunset Yellow FCF], FD&C Blue No.1 [Brilliant Blue FCF] and FD&C Red No.3 [Erythrosine] |

3.2 Product Description

| Brand name | OHSUGI Tokishakuyakusanryo Extract Granules G | OHSUGI Tokishakuyakusanryo Extract T Tablets |
|-------------|--|--|
| Dosage form | Granules | Film-coated tablets |
| Tone | Light grayish and dark brown to light grayish brown-colored granules | Light brown-colored film-coated tablets |
| Smells | Slightly | - |
| Tastes | Slightly sweet and bitter and the taste remains | - |
| Form | - | Front |
| | | Back |
| Diameter | - | About 9.0 mm |
| Thickness | - | About 5.4 mm |
| Weight | - | About 330 mg |
| ID Code | SG-23 | SG-23T |

4. INDICATIONS

The following symptoms in patients who have relatively poor physical strength, with sensitivity to cold, tendency for anemia, fatigue, and sometimes complaint of lower abdominal pain, dull headaches, dizziness, shoulder muscle stiffness, tinnitus, palpitation, etc.:
Menstrual irregularity, menstrual abnormality, menstrual pain, climacteric disturbance, disorders before and after childbirth or miscarriage (anemia, fatigue, malaise, dizziness, swelling), dizziness, dull headache, shoulder muscle stiffness, low back pain, coldness in the legs, chilblains, swelling, and chloasma

6. DOSAGE AND ADMINISTRATION

< OHSUGI Tokishakuyakusanryo Extract Granules G >

The usual adult dose is 7.5 g/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

< OHSUGI Tokishakuyakusanryo Extract T Tablets >

The usual adult dose is 18 tablets/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

8. IMPORTANT PRECAUTIONS

8.1 When this product is used, the patient's "SHO" (constitution/symptoms) should be taken into consideration. The patient's progress should be carefully monitored, and if no improvement in symptoms or findings is observed, continuous administration should be avoided.

8.2 When this product is used in combination with other Kampo products, 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 products should be used after confirmation that it is suitable for the identified "SHO" of the patient.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS**9.1 Patients with Complication or History of Diseases, etc.****9.1.1 Patients with an extremely weak gastrointestinal tract**

Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc. may occur.

9.1.2 Patients with anorexia, nausea, or vomiting

These symptoms may be aggravated.

9.5 Pregnant Women

This product should be used in pregnant women or women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

9.6 Breast-feeding Women

Considering the therapeutic benefits and the benefits of breastfeeding, continuation or discontinuation of breastfeeding should be considered.

9.7 Pediatric Use

No clinical studies have been conducted in children.

9.8 Geriatric Use

Since the physiological functions are generally decreased in elderly patients, careful supervision is recommended; measures such as reducing the dose may be considered.

11. ADVERSE REACTIONS

The following adverse reactions may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

11.2 Other Adverse Reactions

| | Frequency unknown |
|------------------|---|
| Hypersensitivity | Rash, pruritus, etc. |
| Liver | Hepatic function abnormal (increased AST, ALT, etc.) |
| Gastrointestinal | Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc. |

20. PRECAUTIONS FOR HANDLING

20.1 To maintain the quality of the product, avoid moisture as much as possible and store in a cool place, away from direct sunlight.

20.2 Avoid moisture, especially after opening, and handle with care.

20.3 Since this product is made from crude drugs, the color of the product may vary.

22. PACKAGING

< OHSUGI Tokishakuyakusanryo Extract Granules G >

500 g [Bottle]

735 g (2.5 g × 294 packets) [Sachet]

210 g (2.5 g × 84 packets) [Sachet]

< OHSUGI Tokishakuyakusanryo Extract T Tablets >

1,764 tablets (6 tablets × 294 packets) [Sachet]

504 tablets (6 tablets × 84 packets) [Sachet]

24. REFERENCE REQUEST AND CONTACT INFORMATION

Dep. of PMS Information,

Ohsugi Pharmaceutical Co., Ltd.

1-8-6, Yamasaka, Higashiumiyoshi-ku, Osaka 546-0035

06-6629-9058

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Marketing Authorization Holder

Ohsugi Pharmaceutical Co., Ltd.

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