Revised：February 2022 (1st version)

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

-Kampo product-

SG-84

# OHSUGI Daiokanzoto
## Extract Granules G

SG-84T

# OHSUGI Daiokanzoto
## Extract T Tablets

(Daiokanzoto)

Storage：Store at room temperature

Shelf Life：3 years

| | Approval No. | Date of Initial Marketing in Japan |
|---|---|---|
| Granules G | 16100AMZ04809000 | October 1987 |
| T Tablets | 16100AMZ04184000 | October 1986 |

### 3. COMPOSITION AND PRODUCT DESCRIPTION

**3.1 Composition**

| Brand name | OHSUGI Daiokanzoto Extract Granules G | OHSUGI Daiokanzoto Extract T Tablets |
|---|---|---|
| Active ingredient | The daily dose of this product, 3.0 g, contains 0.8 g of the dried extract (Daiokanzoto extract) from the following mixed crude drugs. | The daily dose of this product, 6 tablets, contains 0.8 g of the dried extract (Daiokanzoto extract) from the following mixed crude drugs. |
| | JP Rhubarb 4 g<br>JP Glycyrrhiza 1 g<br>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 Daiokanzoto Extract Granules G | OHSUGI Daiokanzoto Extract T Tablets | | |
|---|---|---|---|---|
| Dosage form | Granules | Film-coated tablets | | |
| Tone | Light grayish brown to light grayish dark brown-colored granules | Light brown-colored film-coated tablets | | |
| Smells | Uniquely | - | | |
| Tastes | Slightly sweet, bitter and astringent | - | | |
| Form | - | Front | Back | Side |
| | |  |  |  |
| Diameter | - | About 9.0 mm | | |
| Thickness | - | About 5.4 mm | | |
| Weight | - | About 330 mg | | |
| ID Code | ＳＧ－８４ | ＳＧ－８４Ｔ | | |

### 4. INDICATIONS

**Constipation**

### 6. DOSAGE AND ADMINISTRATION

< OHSUGI Daiokanzoto Extract Granules G >

The usual adult dose is 3.0 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 Daiokanzoto Extract T Tablets >

The usual adult dose is 6 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** Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc. [See Sections 10.2, 11.1.1, 11.1.2]

**8.3** When this product is used in combination with other Kampo products, etc., attention should be paid to the duplication of the contained crude drugs. Special attention should be paid to concomitant use with preparations containing Rhubarb.

**8.4** Since there are individual differences in the cathartic action of Rhubarb, caution should be exercised with respect to 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 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 diarrhea, loose stools**

These symptoms may be aggravated.

**9.1.2 Patients with an extremely weak gastrointestinal tract**

Anorexia, abdominal pain, diarrhea, etc. may occur.

**9.1.3 Patients with extremely weakened constitution**

Adverse reactions are likely to occur, and the symptoms may be aggravated.

**9.5 Pregnant Women**

It is not recommended to administer this product to pregnant women or women who may possibly be pregnant. There is a risk of premature birth or miscarriage due to the uterotonic action and hyperemic action of the pelvic organs of Rhubarb contained in this product.

**9.6 Breast-feeding Women**

Considering the therapeutic benefits and the benefits of breastfeeding, continuation or discontinuation of breastfeeding should be considered. Anthraquinone derivatives in Rhubarb contained in this product are excreted in breast milk and may cause diarrhea in infants.

**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.

**10. INTERACTIONS**

**10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)**

| Drugs | Signs, Symptoms, and Treatment | Mechanism and Risk Factors |
|---|---|---|
| Glycyrrhiza-containing preparations<br>Shakuyakukanzoto<br>Hochuekkito<br>Yokukansan, etc.<br>Preparations containing glycyrrhizic acid and its salts<br>Monoammonium Glycyrrhizinate/Glycine/ L-cysteine<br>Monoammonium Glycyrrhizinate/Glycine/ DL-Methionine combination tablets, etc.<br>[See Sections 8.2, 11.1.1, 11.1.2] | Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur. | Since glycyrrhizic acid has an accelerating effect on potassium excretion in the renal tubules, an acceleration of decrease in the serum potassium level has been suggested. |

**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.

**11.1 Clinically Significant Adverse Reactions**

**11.1.1 Pseudoaldosteronism** (frequency unknown)

Pseudoaldosteronism such as hypokalaemia, blood pressure increased, retention of sodium/body fluid, edema, and body weight gain may occur. Patients should be carefully monitored (e.g., measurement of serum potassium levels), and if any abnormalities are observed, administration should be discontinued, and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

**11.1.2 Myopathy** (frequency unknown)

Myopathy may occur as a result of hypokalaemia. Patients should be carefully monitored, and if any abnormalities such as feelings of weakness, muscle cramp in extremities, or paralysis are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

**11.2 Other Adverse Reactions**

| | Frequency unknown |
|---|---|
| Gastrointestinal | Anorexia, abdominal pain, diarrhea, etc. |

**17. CLINICAL STUDIES**

**17.2 Post-marketing Surveillance, etc.**

**17.2.1 Domestic post-marketing clinical trials**

In a double-blind, controlled clinical trial in patients diagnosed with constipation, the drug performed as follows.[1)]

| | efficacy rate (%) |
|---|---|
| Daiokanzoto group | 86.4 (38/44) |
| Placebo group | 44.7 (21/47) |

**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 Daiokanzoto Extract Granules G >

500 g［Bottle］
294 g （1.0 g × 294 packets）［Sachet］
84 g （1.0 g × 84 packets）［Sachet］

< OHSUGI Daiokanzoto Extract T Tablets >

588 tablets （2 tablets × 294 packets）［Sachet］
168 tablets （2 tablets × 84 packets）［Sachet］

**24. REFERENCE REQUEST AND CONTACT INFORMATION**

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., Ltd.
1-8-6, Yamasaka, Higashisumiyoshi-ku, Osaka 546-0035
06-6629-9058

**26. MARKETING AUTHORIZATION HOLDER, etc.**

**26.1 Marketing Authorization Holder**

Ohsugi Pharmaceutical Co., Ltd.
1-1-2, Tennojichominami Abeno-ku, Osaka 545-0002