Revised：February 2022 (1st version)

Standard Commodity Classification No. of Japan
875200

-Kampo product-

SG-08

OHSUGI Daisaikoto
Extract Granules G

SG-08T

OHSUGI Daisaikoto
Extract T Tablets

(Daisaikoto)

	Approval No.	Date of Initial Marketing in Japan
Granules G	16100AMZ04821000	October 1987
T Tablets	16100AMZ04182000	October 1986

Storage：Store at room temperature

Shelf Life：3 years

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	OHSUGI Daisaikoto Extract Granules G	OHSUGI Daisaikoto Extract T Tablets
Active ingredient	The daily dose of this product, 7.5 g, contains 3.9 g of the dried extract (Daisaikoto extract) from the following mixed crude drugs.	The daily dose of this product, 18 tablets, contains 4.0 g of the dried extract (Daisaikoto extract) from the following mixed crude drugs.
	JP Bupleurum Root 6 g JP Pinellia Tuber 4 g JP Ginger 1 g JP Scutellaria Root 3 g JP Peony Root 3 g JP Jujube 3 g JP Immature Orange 2 g JP Rhubarb 1 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 Daisaikoto Extract Granules G	OHSUGI Daisaikoto Extract T Tablets		
Dosage form	Granules	Film-coated tablets		
Tone	Light grayish yellowish brown to light grayish dark brown-colored granules	Light brown-colored film-coated tablets		
Smells	Uniquely	-		
Tastes	Sweet and bitter	-		
Form	-	Front	Back	Side
				
Diameter	-	About 9.0 mm		
Thickness	-	About 5.4 mm		
Weight	-	About 330 mg		
ID Code	ＳＧ－０８	ＳＧ－０８Ｔ		

4. INDICATIONS

The following symptoms in patients who have well-built, relatively physically strong patients with a tendency to constipation:
Gastritis, habitual constipation, shoulder muscle stiffness/headache/constipation associated with hypertension, shoulder muscle stiffness, obesity

6. DOSAGE AND ADMINISTRATION

< OHSUGI Daisaikoto 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 Daisaikoto 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. Special attention should be paid to concomitant use with preparations containing Rhubarb.

8.3 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.

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 Interstitial pneumonia (frequency unknown)

If cough, dyspnea, pyrexia, abnormal lung sound, etc. are observed, administration of this product should be discontinued, and examinations such as chest X-ray and chest CT scan should be performed immediately, and appropriate measures such as administration of corticosteroid should be taken. In addition, patients should be advised to discontinue administration of this product and contact the physician immediately if cough, dyspnea, or pyrexia, etc. occur.

11.1.2 Hepatic impairment, jaundice (frequency unknown)

Hepatic impairment and/or jaundice with marked elevations of AST, ALT, Al-P, γ-GTP, etc. may occur.

11.2 Other Adverse Reactions

	Frequency unknown
Gastrointestinal	Anorexia, 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 Daisaikoto Extract Granules G >

500 g［Bottle］
735 g （2.5 g × 294 packets）［Sachet］
210 g （2.5 g × 84 packets）［Sachet］

< OHSUGI Daisaikoto 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, 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