Revised：August 2022 (1st version)

Standard Commodity Classification No. of Japan
875200

-Kampo product-

SG-15

OHSUGI Orengedokuto
Extract Granules G

SG-15T

OHSUGI Orengedokuto
Extract T Tablets

(Orengedokuto)

Storage：Store at room temperature

Shelf Life：3 years

	Approval No.	Date of Initial Marketing in Japan
Granules G	16100AMZ03879000	October 1986
T Tablets	16100AMZ04189000	October 1986

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	OHSUGI Orengedokuto Extract Granules G	OHSUGI Orengedokuto Extract T Tablets
Active ingredient	The daily dose of this product, 4.5 g, contains 1.7 g of the dried extract (Orengedokuto extract) from the following mixed crude drugs.	The daily dose of this product, 15 tablets, contains 1.7 g of the dried extract (Orengedokuto extract) from the following mixed crude drugs.
	JP Coptis Rhizome 1.5 g JP Phellodendron Bark 3 g JP Scutellaria Root 3 g JP Gardenia Fruit 3 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 Orengedokuto Extract Granules G	OHSUGI Orengedokuto Extract T Tablets		
Dosage form	Granules	Film-coated tablets		
Tone	Light grayish and yellowish brown to light grayish dark brown-colored granules	Light brown-colored film-coated tablets		
Smells	Slightly	-		
Tastes	Extremely bitter lingeringly, and dyes the saliva yellow	-		
Form	-	Front	Back	Side
				
Diameter	-	About 9.0 mm		
Thickness	-	About 5.4 mm		
Weight	-	About 310 mg		
ID Code	ＳＧ－１５	ＳＧ－１５Ｔ		

4. INDICATIONS

The following symptoms in patients who have relatively good physical strength, have a tendency to have hot flushes and red face, and tend to be irritable:

Epistaxis, hypertension, Insomnia, neurotic disorder, gastritis, hangover, menopausal and female climacteric states, dizziness, palpitations, eczema/dermatitis, cutaneous pruritus

6. DOSAGE AND ADMINISTRATION

< OHSUGI Orengedokuto Extract Granules G >

The usual adult dose is 4.5 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 Orengedokuto Extract T Tablets >

The usual adult dose is 15 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 Prolonged administration of preparations containing Gardenia Fruit (for more than 5 years in most cases) may cause mesenteric phlebosclerosis with pigmentation, edema, erosion, ulceration, and stenosis of the colon. In the case of long-term administration, periodic examinations such as CT and colonoscopy are recommended. [See Section 11.1.3]

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.

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 extremely weakened constitution

Adverse reactions are likely to occur, and the 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.

11.1 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.

11.1.3 Mesenteric phlebosclerosis (frequency unknown)

Mesenteric phlebosclerosis may occur with long-term administration of this product. If abdominal pain, diarrhea, constipation, abdominal distension, etc. are repeatedly observed, or if fecal occult blood test is positive, administration should be discontinued, and examinations such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases. [See Section 8.2]

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, urticaria, 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 Orengedokuto Extract Granules G >

500 g［Bottle］
441 g （1.5 g × 294 packets） ［Sachet］
126 g （1.5 g × 84 packets） ［Sachet］

< OHSUGI Orengedokuto Extract T Tablets >

1,470 tablets（5 tablets × 294 packets） ［Sachet］
420 tablets （5 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