

## -Kampo product-

SG-01

**OHSUGI Kakkonto**  
Extract Granules G

SG-01 T

**OHSUGI Kakkonto**  
Extract T Tablets  
(Kakkonto)

Storage : Store at room temperature

Shelf Life : 3 years

	Approval No.	Date of Initial Marketing in Japan
Granules G	16100AMZ03880000	October 1986
T Tablets	16200AMZ00179000	October 1987

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

Brand name	OHSUGI Kakkonto Extract Granules G	OHSUGI Kakkonto Extract T Tablets
Active ingredient	The daily dose of this product, 7.5 g, contains 3.3 g of the dried extract (Kakkonto extract) from the following mixed crude drugs.	The daily dose of this product, 15 tablets, contains 3.3 g of the dried extract (Kakkonto extract) from the following mixed crude drugs.
	JP Pueraria Root	4 g
	JP Ephedra Herb	3 g
	JP Jujube	3 g
	JP Cinnamon Bark	2 g
	JP Peony Root	2 g
	JP Glycyrrhiza	2 g
	JP Ginger	1 g
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 Kakkonto Extract Granules G	OHSUGI Kakkonto Extract T Tablets
Dosage form	Granules	Film-coated tablets
Tone	Light grayish yellow-brown to light grayish dark brown-colored granules	Light brown-colored film-coated tablets
Smells	Uniquely	-
Tastes	Hot initially and then sweet slightly	-
Form	-	Front
		Back
Diameter	-	About 9.0 mm
Thickness	-	About 5.4 mm
Weight	-	About 310 mg
ID Code	SG-01	SG-01T

**4. INDICATIONS**

**Common cold, head cold, headache, shoulder muscle stiffness, myalgia, hand and shoulder pain**

**6. DOSAGE AND ADMINISTRATION**

< OHSUGI Kakkonto 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 Kakkonto 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** 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.

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 in a period of weakness after disease or with extremely weakened constitution**

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

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

Anorexia, epigastric distress, nausea, vomiting, etc. may occur.

**9.1.3 Patients with anorexia, nausea, or vomiting**

These symptoms may be aggravated.

**9.1.4 Patients with a significant sweating tendency**

Excessive sweating, systemic weakness, etc. may occur.

**9.1.5 Patients with cardiovascular disorders, including angina pectoris or myocardial infarction, or patients with a history of such disorders**

The disease and its symptoms may be aggravated.

### 9.1.6 Patients with severe hypertension

The disease and its symptoms may be aggravated.

### 9.1.7 Patients with urination impaired

The disease and its symptoms may be aggravated.

### 9.1.8 Patients with hyperthyroidism

The disease and its symptoms may be aggravated.

## 9.2 Patients with Renal Impairment

### 9.2.1 Patients with severe renal disorder

The disease and its 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.

## 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
Ephedra Herb-containing preparations Shoseiryuto Maoto Maobushisaishinto, etc. Ephedrine-containing preparations Ephedrine Hydrochloride dl-Methyl Ephedrine Hydrochloride Fexofenadine Hydrochloride/ Pseudoephedrine Hydrochloride, etc. Monoamine Oxidase (MAO) inhibitors Selegiline Hydrochloride Rasagiline Mesilate, etc. Thyroid gland preparations Thyroxine Liothyronine, etc. Catecholamine preparations Adrenaline Isoprenaline, etc. Xanthine preparations Theophylline Diprophylline, etc.	Since insomnia, excessive sweating, tachycardia, palpitation, systemic weakness, mental excitement, etc. are likely to occur, this product should be administered with care by reducing the dosage, etc.	The sympathomimetic effect may be enhanced.

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Glycyrrhiza-containing preparations Shakuyakukanzoto Hochuekkito Yokukansan, etc. Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/ L-cysteine Monoammonium Glycyrrhizinate/Glycine/ DL-Methionine combination tablets, etc. [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]

#### 11.1.3 Hepatic impairment, jaundice (frequency unknown)

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

### 11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, redness, pruritus, etc.
Autonomic	Insomnia, excessive sweating, tachycardia, palpitations, systemic weakness, mental excitement, etc.
Gastrointestinal	Anorexia, epigastric distress, nausea, vomiting, etc.
Urinary	Urination impaired, etc.

## 15. OTHER PRECAUTIONS

### 15.1 Information Based on Clinical Use

Eczema or dermatitis may be aggravated.

## 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 Kakkonto Extract Granules G >

500 g [Bottle]

735 g (2.5 g × 294 packets) [Sachet]

210 g (2.5 g × 84 packets) [Sachet]

< OHSUGI Kakkonto 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