Revised：March 2022 (1st version)

Standard Commodity Classification No. of Japan
875200

-Kampo product-

SG-19

OHSUGI Shoseiryuto Extract Granules G

SG-19T

OHSUGI Shoseiryuto Extract T Tablets

(Shoseiryuto)

	Approval No.	Date of Initial Marketing in Japan
Granules G	16100AMZ03886000	October 1986
T Tablets	16200AMZ00180000	October 1987

Storage：Store at room temperature

Shelf Life：3 years

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)

2.1 Patients with aldosteronism
[The disease and its symptoms may be aggravated.]

2.2 Patients with myopathy
[The disease and its symptoms may be aggravated.]

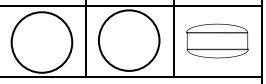
2.3 Patients with hypokalaemia
[The disease and its symptoms may be aggravated.]

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	OHSUGI Shoseiryuto Extract Granules G	OHSUGI Shoseiryuto Extract T Tablets
Active ingredient	The daily dose of this product, 7.5 g, contains 4.1 g of the dried extract (Shoseiryuto extract) from the following mixed crude drugs.	The daily dose of this product, 18 tablets, contains 4.1 g of the dried extract (Shoseiryuto extract) from the following mixed crude drugs.
	JP Ephedra Herb 3 g JP Peony Root 3 g JP Processed Ginger 3 g JP Glycyrrhiza 3 g JP Cinnamon Bark 3 g JP Asiasarum Root 3 g JP Schisandra Fruit 3 g JP Pinellia Tuber 6 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 Shoseiryuto Extract Granules G	OHSUGI Shoseiryuto Extract T Tablets
Dosage form	Granules	Film-coated tablets
Tone	Light yellowish brown to light grayish brown-colored granules	Light brown-colored film-coated tablets
Smells	Slightly	-
Tastes	Slightly acidic, bitter and hot. The taste remains	-
Form	-	Front / Back / Side 
Diameter	-	About 9.0 mm
Thickness	-	About 5.4 mm
Weight	-	About 330 mg
ID Code	ＳＧ－１９	ＳＧ－１９Ｔ

4. INDICATIONS

The following symptoms in patients with watery sputum, watery nasal discharge, nasal congestion, sneeze, wheezing, cough, lacrimation in the following diseases:
Bronchitis, bronchial asthma, rhinitis, allergic rhinitis, allergic conjunctivitis, common cold

6. DOSAGE AND ADMINISTRATION

< OHSUGI Shoseiryuto 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 Shoseiryuto 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 Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc. [See Sections 10.2, 11.1.2, 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 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, abdominal pain, diarrhea, 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 Kakkonto 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.
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. Loop diuretics Azosemide Torasemide Furosemide, etc. Thiazide diuretics Trichlormethiazide Hydrochlorothiazide Benzylhydrochlorothiazide, etc. [See Sections 8.2, 11.1.2, 11.1.3]	Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur.	Since glycyrrhizic acid and diuretics promote potassium excretion in renal tubules, it is considered that a decrease in the serum potassium level may be promoted.

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 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]

11.1.3 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]

11.1.4 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
Hypersensitivity	Rash, redness, pruritus, etc.
Autonomic	Insomnia, excessive sweating, tachycardia, palpitations, systemic weakness, mental excitement, etc.
Gastrointestinal	Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc.
Urinary	Urination impaired, 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 for perennial nasal allergy, this drug improved symptoms such as sneezing attacks, nasal discharge, and nasal obstruction, and the final overall improvement rate was as follows.[1)]

	Improvement rate (%)	
	(Moderate or higher improvement)	(More than mild improvement)
Shoseiryuto group	44.6 (41/92)	83.7 (77/92)
Placebo group	18.1 (17/94)	43.6 (41/94)

18. PHARMACOLOGY

18.1 Mechanism of Action

The mechanism of action is not clear.

18.2 Antihistamine action (effect)

Degranulation from mast cells pretreated with the drug was inhibited. The drug inhibited histamine release by DNP-As antigen and Compound 48/80 from rat mast cells. *(in vitro)*[2)]

18.3 Antiallergic action

The drug inhibited 48 hr homorogous PCA reaction with serum containing rat anti-DNP-As and IgE antibodies. *(in vitro)*[2)]

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 Shoseiryuto Extract Granules G >

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

< OHSUGI Shoseiryuto Extract T Tablets >

1,764 tablets （6 tablets × 294 packets） ［Sachet］
504 tablets （6 tablets × 84 packets） ［Sachet］

23. REFERENCES

1) Shunkichi Baba et al. Practica Otologica. 1995; 88(3): 389-405.
2) Tatsuji Matsumoto et al. OTO-RHINO-LARYNGOLOGY, TOKYO. 1991; 34(suppl.4): 289-293.

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.
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