

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ04760000
Date of Initial Marketing in Japan	Oct. 1987

Kampo product

JPS Shoseiryuto Extract Granules for Ethical Use

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

Product Name	JPS Shoseiryuto Extract Granules for Ethical Use		
Active Ingredients	JP Ephedra Herb	3.0 g	
	JP Peony Root	3.0 g	
	JP Ginger	3.0 g	
	JP Glycyrrhiza	3.0 g	
	JP Cinnamon Bark	3.0 g	
	JP Asiasarum Root	3.0 g	
	JP Schisandra Fruit	3.0 g	
	JP Pinellia Tuber	6.0 g	
	7.5 g/day of this product contains 5.0 g of a dried JP Shoseiryuto extract of the above mixed crude drugs.		
	Inactive Ingredients	Mg Stearate, Sucrose Esters of Fatty Acids, Lactose Hydrate	

3.2 Product Description

Dosage Form	Granules
Color	Dark brown
Smell	Characteristic smell
Taste	Slightly acid and bitter
ID Code	J-19

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

The usual adult dose is 7.5 g/day orally in 2 or 3 divided doses before or between meals. The dosage may be adjusted according to the patient's age and 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 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.

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 its 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 Brest-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.
Preparations containing Glycyrrhiza Shakuyakukanzoto Hochuekkito Yokukansan, etc. Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/L-cysteine Monoammonium Glycyrrhizinate/Glycine/DL-methionine combination	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

tablets, etc. Loop diuretics Azosemide Torasemide Furosemide, etc. Thiazide diuretics Trichlormethiazide Hydrochlorothiazide Benzylhydrochlorothiazide, etc. [See 8.2, 11.1.2, 11.1.3]		promoted.
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INFORMATION

JPS Pharmaceutical CO., LTD
4-42-22 Higashiyamata, Tsuzukiku, Yokohama City, Kanagawa Prefecture
224-0023, Japan
TEL : 045-593-2060

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Manufactured and Distributed by:

JPS Pharmaceutical CO., LTD
196-1 Hagadai, Hagamachi, Hagagun, Tochigi Prefecture 321-3325, Japan

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 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 8.2, 10.2]

11.1.4 Hepatic impairment, jaundice (frequency unknown)

Hepatic impairment and/or jaundice with marked elevations of AST, ALT, ALP, 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 Post-marketing clinical studies in Japan

Shoseiryuto improved paroxysmal sneezing, nasal discharge, and nasal obstruction in a double-blind comparative study on perennial nasal allergy. The final global improvement rate is shown below. ¹⁾

	Rate of Improvement (%)	
	“Moderately improved” or better evaluations	“Slightly Improved” or better evaluations
Shoseiryuto group	44.6 (41/92)	83.7 (77/92)
Placebo group	18.1 (17/94)	43.6 (41/94)

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

500 g

750 g (2.5 g × 300 packets)

105 g (2.5 g × 42 packets)

23. REFERENCES

1) Baba, S. et al. Practica Otologica. 1995, 88(3), p.389.

24. REFERENCE REQUEST AND CONTACT