

Storage: Store at room temperature

Shelf Life: 3 years

Kampo product

Approval No.	16100AMZ03815000
Date of Initial Marketing in Japan	October 1986

N19

Kotaro Shoseiryuto Extract Fine Granules

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	Kotaro Shoseiryuto Extract Fine Granules
Active ingredient	7.5g of Kotaro Shoseiryuto Extract Fine Granules contains 5.0g of the dried extract of the following mixed crude drugs. JP Ephedra Herb..... 3.0g JP Peony Root..... 3.0g JP Processed Ginger 3.0g JP Glycyrrhiza..... 3.0g JP Cinnamon Bark..... 3.0g JP Asiasarum Root..... 3.0g JP Schisandra Fruit..... 3.0g JP Pinellia Tuber..... 6.0g (JP: Japanese Pharmacopoeia)
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

3.2 Product Description

Dosage form	Fine granules
Color	Dark brown to yellowish brown
Taste	Acidic
Odor	Characteristic odor
ID code	N19

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 dosage for oral use is 7.5g daily in 2 or 3 divided doses 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.

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 decrease 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 Benzyhydrochlorothiazide, 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 the 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 Shoseiryuto improved paroxysmal sneeze, nasal discharge, and nasal congestion in a double-blind comparative study on perennial nasal allergy. The final global improvement rate is shown below. The incidence of adverse reactions was 6.5% (7/107 patients) in the drug group and 6.4% (7/110 patients) in the placebo group, and the main adverse reactions in the drug group were gastrointestinal symptoms (4 patients)¹⁾.

	Rate of Improvement (%)	
	“Moderately improved” or better evaluation	“Slightly Improved” or better evaluation
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

500g [bottle, loose]

2.5g×42 packets [sachets]

2.5g×189 packets [sachets]

23. REFERENCES

1) S. Baba et al.: Practica Otologica, 1995 ; 88 (3) : 389-405

24. REFERENCE REQUEST AND CONTACT INFORMATION

Pharmaceutical Division, Kotaro Pharmaceutical Co., Ltd.

5-23, Nakatsu 2-chome, Kita-ku, Osaka 531-0071, Japan

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Marketing Authorization Holder

Kotaro Pharmaceutical Co., Ltd.

5-23, Nakatsu 2-chome, Kita-ku, Osaka 531-0071, Japan