

Storage: Store at room temperature
 Shelf Life: 3 years

Approval No.	16100AMZ03819000
Date of Initial Marketing in Japan	October 1986

Kampo product

N2

Kotaro Kakkontokashin'isenkyu Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Kakkontokashin'isenkyu Extract Fine Granules
Active ingredient	9.0g of Kotaro Kakkontokashin'isenkyu Extract Fine Granules contains 5.8g of the dried extract of the following mixed crude drugs.
	JP Pueraria Root..... 4.0g
	JP Ephedra Herb 4.0g
	JP Cinnamon Bark 2.0g
	JP Peony Root..... 2.0g
	JP Jujube..... 3.0g
	JP Ginger..... 1.0g
	JP Glycyrrhiza..... 2.0g
	JP Cnidium Rhizome..... 3.0g
	JP Magnolia Flower 3.0g
(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	Slightly sweet and bitter
Odor	Characteristic odor
ID code	N2

4. INDICATIONS

Empyema, chronic rhinitis, nasal congestion.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 9.0g 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, 11.1.1, 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.

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, 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 Shoseiryuto Maoto 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.
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.		

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]	Pseudo-aldosteronism 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.

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

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]

11.2 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, Diarrhea, 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

500g [bottle, loose]

3.0g×42 packets [sachets]

3.0g×168 packets [sachets]

24. REFERENCE REQUEST AND CONTACT INFORMATION

Pharmaceutical Division, Kotaro Pharmaceutical Co., Ltd.

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