

Storage: Store at room temperature

Shelf Life: 3 years

Kampo product

Approval No.	16100AMZ03956000
Date of Initial Marketing in Japan	October 1986

N22

Kotaro Shofusan Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Shofusan Extract Fine Granules
Active ingredient	9.0g of Kotaro Shofusan Extract Fine Granules contains 6.0g of the dried extract of the following mixed crude drugs.
	JP Japanese Angelica Root.....3.0g
	JP Rehmannia Root 3.0g
	JP Gypsum.....3.0g
	JP Glehnia Root and Rhizome2.0g
	JP Atractylodes Lancea Rhizome.....2.0g
	JP Akebia Stem.....2.0g
	JP Burdock Fruit.....2.0g
	JP Anemarrhena Rhizome..... 1.5g
	JP Sesame.....1.5g
	Cicada Slough.....1.0g
	JP Sophora Root.....1.0g
	JP Schizonepeta Spike1.0g
	JP Glycyrrhiza.....1.0g
(JP: Japanese Pharmacopoeia)	
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

3.2 Product Description

Dosage form	Fine granules
Color	Blackish brown to deep brown
Taste	Sweet and hot
Odor	Characteristic odor
ID code	N22

4. INDICATIONS

The following symptoms in patients with the conditions below: intractable skin disease that has persisted for many years, in which the affected area is dry or has thin secretion and is likely to worsen in summer or warm weather.

Eczema, urticaria.

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 with a weak gastrointestinal tract

Anorexia, epigastric distress, nausea, vomiting, loose stools, diarrhea, etc. may occur.

9.1.2 Patients with anorexia, nausea, or vomiting

These symptoms may be aggravated.

9.1.3 Patients with extremely weakened constitution

Adverse reactions are likely to occur, and the 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
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]

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, Pruritus, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Loose stools, Diarrhea, etc.

15. OTHER PRECAUTIONS

15.1 Information Based on Clinical Use

A skin disease in which the affected area is dry, and symptoms may worsen.

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

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