

Storage: Store at room temperature

Shelf Life:3 years

Kampo product

N108

Approval No.	16100AMZ03817000
Date of Initial Marketing in Japan	October 1986

## Kotaro Ninjin'yoeito Extract Fine Granules

### 3. COMPOSITION AND PRODUCT DESCRIPTION

#### 3.1 Composition

Brand name	Kotaro Ninjin'yoeito Extract Fine Granules
Active ingredient	15.0g of Kotaro Ninjin'yoeito Extract Fine Granules contains 9.2g of the dried extract of the following mixed crude drugs.
	JP Ginseng ..... 3.0g
	JP Japanese Angelica Root ..... 4.0g
	JP Peony Root..... 2.0g
	JP Rehmannia Root..... 4.0g
	JP Atractylodes Rhizome..... 4.0g
	JP Poria Sclerotium..... 4.0g
	JP Cinnamon Bark ..... 2.5g
	JP Astragalus Root ..... 1.5g
	JP Citrus Unshiu Peel ..... 2.0g
	JP Polygala Root..... 2.0g
	JP Schisandra Fruit ..... 1.0g
	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	Dark brown to yellowish brown
Taste	Slightly sweet
Odor	Characteristic odor
ID code	N108

### 4. INDICATIONS

In thin and pale patients with the following symptoms: mild fever, chills, and persisting cough, marked malaise, anorexia, mental anxiety, insomnia, severe night sweats, and tendency for constipation. For increase in physical strength after illness or childbirth, weak constitution.

### 6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 15.0g 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 an extremely weak gastrointestinal tract

Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc. may occur.

##### 9.1.2 Patients with anorexia, nausea, or vomiting

These 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]

### 11.1.3 Hepatic impairment, jaundice (frequency unknown)

Hepatic impairment and/or jaundice with marked elevations of AST, ALT, Al-P,  $\gamma$ -GTP, etc. may occur.

### 11.2 Other Adverse Reactions

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

## 12. INFLUENCE ON LABORATORY TESTS

Administration of this product may cause an increase in blood AG (1,5-anhydro-D-glucitol).

## 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]

2.5g×189 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