

Storage: Store at room temperature

Shelf Life: 3 years

Kampo product

Approval No.	16100AMZ03830000
Date of Initial Marketing in Japan	October 1986

N23

## Kotaro Tokishakuyakusanryo Extract Fine Granules

### 3. COMPOSITION AND PRODUCT DESCRIPTION

#### 3.1 Composition

Brand name	Kotaro Tokishakuyakusanryo Extract Fine Granules
Active ingredient	9.0g of Kotaro Tokishakuyakusanryo Extract Fine Granules contains 5.5g of the dried extract of the following mixed crude drugs.
	JP Japanese Angelica Root.....3.0g
	JP Cnidium Rhizome.....3.0g
	JP Peony Root.....4.0g
	JP Poria Sclerotium.....4.0g
	JP Atractylodes Rhizome.....4.0g
	JP Alisma Tuber.....4.0g (JP: Japanese Pharmacopoeia)
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

#### 3.2 Product Description

Dosage form	Fine granules
Color	Light brown to yellowish brown
Taste	Slightly sweet and acidic
Odor	Characteristic odor
ID code	N23

### 4. INDICATIONS

The following symptoms in patients with the conditions below: anemia, sensitivity to cold, weak stomach and intestines, light black eye circles, fatigue, dull headache, dizziness, shoulder muscle stiffness, palpitations, frequent urination, decreased urine output, and dry throat, or cold, with tenderness or pain in the lower abdomen, or susceptibility to frostbite.

Heart failure, kidney diseases, anemia, anemia before and after childbirth or due to miscarriage, hemorrhoids, anal prolapse, mild hyperemesis gravidarum, menstrual irregularity, menstrual pain, climacteric neurosis, acne, chloasma, blood pressure abnormality.

### 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 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.

### 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.

#### 11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Pruritus, etc.
Liver	Hepatic function abnormal (increased AST, ALT, etc.)
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, etc.

### 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