

Storage: Store at room temperature

Shelf Life:3 years

Approval No.	16100AMZ03825000
Date of Initial Marketing in Japan	October 1986

Kampo product

N104

Kotaro Shin'iseihaito Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Shin'iseihaito Extract Fine Granules
Active ingredient	12.0g of Kotaro Shin'iseihaito Extract Fine Granules contains 7.5g of the dried extract of the following mixed crude drugs.
	JP Magnolia Flower.....2.0g
	JP Anemarrhena Rhizome.....3.0g
	JP Lilium Bulb.....3.0g
	JP Scutellaria Root.....3.0g
	JP Gardenia Fruit.....3.0g
	JP Ophiopogon Root.....5.0g
	JP Gypsum.....5.0g
	JP Cimicifuga Rhizome.....1.0g
	JP Loquat Leaf.....2.0g
(JP: Japanese Pharmacopoeia)	
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

3.2 Product Description

Dosage form	Fine granules
Color	Ocher to brown
Taste	Bitter
Odor	Characteristic odor
ID code	N104

4. INDICATIONS

Empyema, chronic rhinitis, nasal congestion.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 12.0 g 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 Prolonged administration of preparations containing Gardenia Fruit (for more than 5 years in most cases) may cause mesenteric phleboscrosis with pigmentation, edema, erosion, ulceration, and stenosis of the colon. In the case of long-term administration, periodic examinations such as CT and colonoscopy are recommended. [See Section 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 with a weak gastrointestinal tract

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

9.1.2 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.

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 Hepatic impairment, jaundice (frequency unknown)

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

11.1.3 Mesenteric phleboscrosis (frequency unknown)

Mesenteric phleboscrosis may occur with long-term administration of this product. If abdominal pain, diarrhea, constipation, abdominal distension, etc. are repeatedly observed, or if fecal occult blood test is positive, administration should be discontinued, and examinations such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases.

[See Section 8.2]

11.2 Other Adverse Reactions

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

4.0g×42 packets[sachets]

4.0g×147 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