

Storage: Store at room temperature

Shelf Life: 3 years

Approval No.	16100AMZ03827000
Date of Initial Marketing in Japan	October 1986

Kampo product

N8

Kotaro Daisaikoto Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Daisaikoto Extract Fine Granules
Active ingredient	9.0g of Kotaro Daisaikoto Extract Fine Granules contains 6.0g of the dried extract of the following mixed crude drugs.
	JP Bupleurum Root..... 6.0g
	JP Pinellia Tuber..... 4.0g
	JP Ginger..... 1.0g
	JP Scutellaria Root 3.0g
	JP Peony Root..... 3.0g
	JP Jujube..... 3.0g
	JP Immature Orange 2.0g
JP Rhubarb 2.0g	
	(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 brown
Taste	Bitter
Odor	Characteristic odor
ID code	N8

4. INDICATIONS

The following symptoms in patients with the conditions below: pressure in the liver area, or a tight feeling in the pit of the stomach, pain or pressure in the chest or flanks, constipation, or conversely diarrhea, and sometimes accompanied by tinnitus, shoulder muscle stiffness, fatigue, or decreased appetite.

Hypertension, arteriosclerosis, habitual constipation, obesity, jaundice, cholelithiasis, cholecystitis, gastrointestinal disease, bronchial asthma, insomnia, neurasthenia, impotence, hemorrhoids, hemiplegia.

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. Special attention should be paid to concomitant use with preparations containing Rhubarb.

8.3 Since there are individual differences in the cathartic action of Rhubarb, caution should be exercised with respect to dosage and administration.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with diarrhea, loose stools

These symptoms may be aggravated.

9.1.2 Patients with an extremely weak gastrointestinal tract

Anorexia, abdominal pain, diarrhea, etc. may occur.

9.1.3 Patients with extremely weakened constitution

Adverse reactions are likely to occur, and the symptoms may be aggravated.

9.5 Pregnant Women

It is not recommended to administer this product to pregnant women or women who may possibly be pregnant. There is a risk of premature birth or miscarriage due to the uterotonic action and hyperemic action of the pelvic organs of Rhubarb contained in this product.

9.6 Breast-feeding Women

Considering the therapeutic benefits and the benefits of breastfeeding, continuation or discontinuation of breastfeeding should be considered. Anthraquinone derivatives in Rhubarb contained in this product are excreted in breast milk and may cause diarrhea in infants.

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.

11.2 Other Adverse Reactions

	Frequency unknown
Gastrointestinal	Anorexia, 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