

Storage: Store at room temperature

*Shelf Life: 3 years

Approval No.	16100AMZ04229000
Date of Initial Marketing in Japan	October 1986

Kampo product

N17

Kotaro Goreisanryo Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Goreisanryo Extract Fine Granules
Active ingredient	6.0g of Kotaro Goreisanryo Extract Fine Granules contains 3.2g of the dried extract of the following mixed crude drugs.
	JP Alisma Tuber.....6.0g
	JP Polyporus Sclerotium.....4.5g
	JP Poria Sclerotium.....4.5g
	JP Atractylodes Rhizome4.5g
	JP Cinnamon Bark2.5g (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	Sweet and bitter
Odor	Characteristic odor
ID code	N17

4. INDICATIONS

The following symptoms in patients with the conditions below: dry throat, and decreased urine output despite drinking water, headache, dull headache, head sweat, nausea, vomiting or edema.
Acute gastrointestinal catarrh, diarrhea in children and infants, hangover, heat rash, jaundice, nephritis, nephrosis, and bladder catarrh.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6.0g 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

9.5 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, Redness, Pruritus, etc.
Liver	Hepatic function abnormal (increased AST, ALT, γ -GTP, 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]
2.0g×42 packets [sachets]
2.0g×231 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