

Storage: Store at room temperature

Shelf Life: 3 years

Kampo product

Approval No.	16100AMZ03803000
Date of Initial Marketing in Japan	October 1986

N25

Kotaro Keishibukuryoganryo Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Keishibukuryoganryo Extract Fine Granules
Active ingredient	6.0g of Kotaro Keishibukuryoganryo Extract Fine Granules contains 2.8g of the dried extract of the following mixed crude drugs. JP Cinnamon Bark.....4.0g JP Poria Sclerotium.....4.0g JP Moutan Bark.....4.0g JP Peach Kernel.....4.0g JP Peony Root.....4.0g (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 hot, and slightly bitter
Odor	Characteristic odor
ID code	N25

4. INDICATIONS

The following symptoms in patients who have relatively good physical strength and sometimes have complaint of lower abdominal pain, shoulder muscle stiffness, dull headache, dizziness, hot flushes, and cold feet:

Menstrual irregularity, menstrual abnormality, menstrual pain, climacteric disturbance, menopausal and female climacteric states, shoulder muscle stiffness, dizziness, dull headache, bruise, chilblains, chloasma.

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

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 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. Peach Kernel and Moutan Bark contained in this product may cause premature birth or miscarriage.

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 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
Hypersensitivity	Rash, Redness, Pruritus, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, 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]
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