Revised: July 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Storage: Store at room temperature
Shelf Life:3 years

Approval No.	16100AMZ03954000
Date of Initial Marketing in Japan	October 1986

Kampo product

N71

Kotaro Shimotsuto Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Shimotsuto Extract Fine Granules
Active ingredient	6.0g of Kotaro Shimotsuto Extract Fine Granules contains 3.5 gof the dried extract of the following mixed crude drugs. JP Japanese Angelica Root ……3.0g JP Peony Root ……3.0g JP Cnidium Rhizome ……3.0g JP Rehmannia Root ……3.0g (JP: Japanese Pharmacopoeia)
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

3.2 Product Description

Dosage form	Fine granules
Color	Grayish brown to brown
Taste	Sweet and hot
Odor	Characteristic odor
ID code	N71

4. INDICATIONS

The following symptoms in patients with the conditions below: anemia or sensitivity to cold, with a soft, slightly bloating abdomen and a tendency toward constipation.

Hypertension, anemia, climacteric disturbance, menstrual irregularity, menstrual pain, heavy menstrual bleeding, and various disorders before and after childbirth.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6.0 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 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, 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
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, 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