Revised: January 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Storage: Store at room temperature
Shelf Life:3 years

Approval No.	16100AMZ03966000
Date of Initial Marketing in Japan	October 1986

Kampo product

N133

Kotaro Daijokito Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Daijokito Extract Fine Granules
Active ingredient	6.0g of Kotaro Daijokito Extract Fine Granules contains 2.3g of the dried extract of the following mixed crude drugs. JP Rhubarb……2.0g JP Immature Orange……2.0g JP Anhydrous Sodium Sulfate……0.9g JP Magnolia Bark……5.0g (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	Hot and bitter
Odor	Characteristic odor
ID code	N133

4. INDICATIONS

The following symptoms in patients with constipation due to hard abdomen or constipation due to obesity:
Habitual constipation, acute constipation, hypertension, neurotic disorder, food poisoning.

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. 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. Rhubarb (uterotonic action and congestive action on pelvic organs) and Anhydrous Sodium Sulfate (uterotonic action) 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. 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.

11.2 Other Adverse Reactions

	Frequency unknown
Gastrointestinal	Anorexia, Abdominal pain, Diarrhea, etc.

15. OTHER PRECAUTIONS

15.1 Information Based on Clinical Use
Since this product contains Anhydrous Sodium Sulfate, caution should be exercised when this product is administered continuously to patients who require dietary salt restriction.

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