Revised: July 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Storage: Store at room temperature.
Shelf Life:3 years

Approval No.	16100AMZ03957000
Date of Initial Marketing in Japan	October 1986

Kampo product

N100

Kotaro Daikenchuto Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Daikenchuto Extract Fine Granules
Active ingredient	27.0g of Kotaro Daikenchuto Extract Fine Granules contains 2.1g of the dried extract of the following mixed crude drugs and 20.0g of JP Koi. JP Japanese Zanthoxylum Peel……2.0g JP Ginseng ……3.0g JP Processed Ginger……5.0g (JP: Japanese Pharmacopoeia)
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

3.2 Product Description

Dosage form	Fine granules
Color	Light brown to milky white
Taste	Sweet
Odor	Characteristic odor
ID code	N100

4. INDICATIONS

The following symptoms in patients with the conditions below: abdominal wall gastrointestinal relaxation, cold sensation in the abdomen, vomiting, bloating, increased peristalsis of the intestines and severe abdominal pain.

Gastroptosis, gastric atony, flaccid diarrhea, flaccid constipation, chronic peritonitis, abdominal pains.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 27.0 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

9.3 Patients with Hepatic Impairment

Hepatic impairment may be exacerbated.

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.

11.1 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.

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
Hypersensitivity	Rash, Urticaria, etc.
Gastrointestinal	Epigastric distress, Nausea, Vomiting, Bloating, 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×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