Revised: January 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Storage: Store at room temperature
Shelf Life:3 years

Approval No.	16100AMZ04024000
Date of Initial Marketing in Japan	October 1986

Kampo product

NC135

Kotaro Inchinkoto Extract Capsules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Inchinkoto Extract Capsules
Active ingredient	6 capsules of Kotaro Inchinkoto Extract Capsules contains 1900mg of the dried extract of the following mixed crude drugs. JP Artemisia Capillaris Flower …… 4.0g JP Gardenia Fruit…… 3.0g JP Rhubarb …… 1.0g (JP: Japanese Pharmacopoeia)
Excipients	Carmellose Calcium, Light Anhydrous Silicic Acid, Microcrystalline Cellulose, Synthetic aluminum Silicate, Magnesium Stearate, Corn Starch, Hydroxypropyl Starch, Magnesium Aluminometasilicate Capsule Materials: Blue No.1 [Brilliant Blue FCF], Yellow No.5 [Sunset Yellow FCF], Titanium Oxide, Gelatin, Sodium Lauryl Sulfate

3.2 Product Description

Dosage form	Hard Capsules
Color	Cap: Deep green, opaque Body: Beige, opaque Contents: Yellowish brown powder
Taste	Contents: Slightly bitter and acidic
Odor	Contents: Characteristic odor
Appearance	
Size	No.1
ID code	NC135

4. INDICATIONS

The following symptoms in patients who have dry throat, chest tightness, constipation, or tenderness in the liver that causes jaundice: Urticaria, stomatitis, and cholecystitis.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6 capsules(2.16g) 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 Prolonged administration of preparations containing Gardenia Fruit (for more than 5 years in most cases) may cause mesenteric phlebosclerosis with pigmentation, edema, erosion, ulceration, and stenosis of the colon. In the case of long-term administration, periodic examinations such as CT and colonoscopy are recommended. [See Section 11.1.2]

8.3 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.

8.4 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, epigastric distress, 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. There is a risk of premature birth or miscarriage due to the uterotonic action and hyperemic action of the pelvic organs of Rhubarb contained in this product.

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.

11.1 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.

11.1.2 Mesenteric phlebosclerosis (frequency unknown)

Mesenteric phlebosclerosis may occur with long-term administration of this product. If abdominal pain, diarrhea, constipation, abdominal distension, etc. are repeatedly observed, or if fecal occult blood test is positive, administration should be discontinued, and examinations such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases. [See Section 8.2]

11.2 Other Adverse Reactions

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

14. PRECAUTIONS CONCERNING USE

14.1 Precautions Concerning the Dispensing of the Drug

For the products that are dispensed in a PTP (press-through package) sheet, instruct the patient to remove the drug from the PTP sheet prior to use. If the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, resulting in severe complications such as mediastinitis.

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.

22. PACKAGING

300capsules(10capsules×30)[PTP]

600capsules(10capsules×60)[PTP]

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.

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