Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Approval No.	16100AMZ03846000
Date of Initial Marketing in Japan	Oct 1986

Kampo product

Kracie Inchinkoto Extract Fine Granules

Storage : Store at room temperature
Shelf Life : 3 years

KB-402 EK-402

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Inchinkoto Extract Fine Granules
Active ingredients	The daily dose of this product (6.0 g) contains 1,400 mg of Inchinkoto extract powder, derived from a mixture of the following crude drugs. JP Rhubarb 1.0 g JP Gardenia Fruit 3.0 g JP Artemisia Capillaris Flower 4.0 g
Inactive Ingredients	JP Magnesium Stearate, JP Microcrystalline Cellulose, JP Lactose Hydrate, Hydrated Silicon Dioxide

(JP: The Japanese Pharmacopoeia)

3.2 Product Description

Dosage form	Fine granules
Color	Light brown to brown
Odor	Characteristic odor
Taste	Slightly sweet and bitter
ID code	KB-402 (3.0 g per sachet) EK-402 (2.0 g per sachet)

4. INDICATIONS

The following symptoms in patients with the conditions below: dry mouth, decreased urine output, and constipation.
Urticaria, stomatitis

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6.0 g daily in two or three 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 of the colon, edema, erosion, ulceration, and stenosis. 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 decreased 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.

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

(KB-402)
3.0 g × 28 packets [sachets]
3.0 g × 168 packets [sachets]
(EK-402)
2.0 g × 42 packets [sachets]
2.0 g × 294 packets [sachets]
500 g [bottle]

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Manufactured and Distributed by:

Kracie, Ltd.
20-20, Kaigan 3-Chome, Minato-ku, Tokyo 108-8080, Japan

26.2 Distributed by:

Kracie Pharmaceutical, Ltd.
20-20, Kaigan 3-Chome, Minato-ku, Tokyo 108-8080, Japan