Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Approval No.	16100AMZ04214000
Date of Initial Marketing in Japan	Oct 1986

Kampo product

Kracie Choreito Extract Fine Granules

Storage : Store at room temperature
Shelf Life : 3 years

KB-40 EK-40

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Choreito Extract Fine Granules
Active ingredients	The daily dose of this product (6.0 g) contains 2,500 mg of Choreito extract powder, derived from a mixture of the following crude drugs. JP Polyporus Sclerotium 3.0 g JP Poria Sclerotium 3.0 g JP Alisma Tuber 3.0 g JP Aluminum Silicate Hydrate with Silicon Dioxide 3.0 g Donkey Glue 3.0 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 yellow-brown to light brown
Odor	Characteristic odor
Taste	Slightly bitter
ID code	KB-40 (3.0 g per sachet) EK-40 (2.0 g per sachet)

4. INDICATIONS

Decreased urine output, difficulty in urinating, and painful micturition or feeling of residual urine

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 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

9.5 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 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.

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, Pruritus, etc.
Gastrointestinal	Epigastric distress, 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-40)
3.0 g × 28 packets [sachets]
3.0 g × 168 packets [sachets]
(EK-40)
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