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Since this translation is prepared in July 2025 based on the Japanese text current at that time, the translation may not reflect the latest information, due to continuous revision of package inserts.

The latest Japanese text is available on PMDA website.

Kracie

Oct 2023 (1st version)

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|--|
| Standard Commodity Classification No. of Japan |
|--|

875200

| | |
|--------------|------------------|
| Approval No. | 16100AMZ03577000 |
|--------------|------------------|

16100AMZ03577000

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|------------------------------------|----------|
| Date of Initial Marketing in Japan | Oct 1986 |
|------------------------------------|----------|

Oct 1986

Kampo product

Kracie Rokumigan ryo Extract Fine Granules

Storage : Store at room temperature
Shelf Life : 3 years

KB-87

EK-87

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

| | | | |
|----------------------|--|-------|--|
| Brand name | Kracie Rokumigan ryo Extract Fine Granules | | |
| Active ingredients | The daily dose of this product (6.0 g) contains 4,200 mg of Rokumigan extract powder, derived from a mixture of the following crude drugs. | | |
| | JP Rehmannia Root | 5.0 g | |
| | JP Cornus Fruit | 3.0 g | |
| | JP Dioscorea Rhizome | 3.0 g | |
| | JP Alisma Tuber | 3.0 g | |
| | JP Poria Sclerotium | 3.0 g | |
| | JP Moutan Bark | 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 | Brown to dark brown |
| Odor | Characteristic odor |
| Taste | Slightly bitter and acid |
| ID code | KB-87 (3.0g per sachet) |
| | EK-87 (2.0g per sachet) |

4. INDICATIONS

The following symptoms in patients who are easily fatigued, have decreased urine output or polyuria, and sometimes have dry mouth:

Dysuria, pollakiuria, swelling, itching

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

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with an extremely weak gastrointestinal tract
Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.

9.1.2 Patients with anorexia, nausea, or vomiting

These 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. Moutan Bark 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.

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 |
| Gastrointestinal | Anorexia, Epigastric distress, Nausea, Vomiting, 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-87)

3.0 g × 28 packets [sachets]

3.0 g × 168 packets [sachets]

(EK-87)

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