Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ03522000
Date of Initial Marketing in Japan	Oct 1986

Powerful drug
[However, this does not include 2.0g packets]

Storage : Store at room temperature
Shelf Life : 3 years

Kampo product

Kracie Hachimijiogan ryo Extract Fine Granules

KB-7 EK-7

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Hachimijiogan ryo Extract Fine Granules	
Active ingredients	The daily dose of this product (6.0 g) contains 5,200 mg of JP Hachimijiogan extract, 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
	JP Cinnamon Bark	1.0 g
	JP Powdered Processed Aconite Root	1.0 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-7 (3.0 g per sachet) EK-7 (2.0 g per sachet)

4. INDICATIONS

The following symptoms in patients who are easily fatigued, with cold limbs, have decreased urine output or polyuria, and sometimes dry mouth:
Leg pain, low back pain, numbness, blurred vision in the elderly, itching, dysuria, polyuria, swelling

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. Special attention should be paid to concomitant use with preparations containing Processed Aconite Root.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with good physical strength
Adverse reactions are likely to occur, and the symptoms may be aggravated.

9.1.2 Patients who are sensitive to heat, have severe hot flushes, and red face
Palpitation, hot flushes, numbness of the tongue, nausea, etc. may occur.

9.1.3 Patients with an extremely weak gastrointestinal tract
Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, constipation, etc. may occur.

9.1.4 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, and adverse reactions of Powdered Processed Aconite Root are likely to occur.

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

This product should be administered with care. This product contains Powdered Processed Aconite Root.

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.
Liver	Hepatic function abnormal (increases in AST, ALT, T-Bil, etc.)
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, Constipation, etc.
Other	Palpitation, Hot flushes, Numbness of the tongue, 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-7)
3.0 g × 28 packets [sachets]
3.0 g × 168 packets [sachets]
(EK-7)
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