Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan	
875200	
Approval No.	21900AMX00642000
Date of Initial Marketing in Japan	Dec 1987

Kampo product

Kracie Hachimijiogan ryo Extract Tablets

Storage : Store at room temperature
Shelf Life : 3 years

EKT-7

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Hachimijiogan ryo Extract Tablets
Active ingredients	The daily dose of this product (18 tablets) 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 Honey, JP Synthetic Aluminum Silicate, JP Magnesium Stearate, JP White Soft Sugar, JP Hypromellose Phthalate, JP Hypromellose, JP Macrogol 6000

(JP: The Japanese Pharmacopoeia)

3.2 Product Description

Dosage form	Film-coated tablets		
Color	Brown to dark brown		
Odor	Practically none		
Taste	Practically none		
Appearance	Surface	Back	Side
			
Diameter	10 mm		
Thickness	5.2 mm		
Mass	401 mg		
ID code	EKT-7		

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 18 tablets 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

252 tablets (3 tablets × 6 packets × 14 sheets) [sachets]
1,764 tablets (3 tablets × 6 packets × 98 sheets) [sachets]

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Manufactured and Distributed by:

OMINEDO PHARMACEUTICAL INDUSTRY CO., LTD.
574, Nenarigaki, Yamatotakada-city, Nara 635-0051, Japan

26.2 Distributed by:

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