Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Approval No.	21900AMX00615000
Date of Initial Marketing in Japan	Oct 1986

Kampo product

Kracie Keishibukuryogan ryo Extract Tablets

Storage : Store at room temperature
Shelf Life : 3 years

EKT-25

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Keishibukuryogan ryo Extract Tablets
Active ingredients	The daily dose of this product (18 tablets) contains 2,200 mg of JP Keishibukuryogan extract, derived from a mixture of the following crude drugs. JP Cinnamon Bark 4.0 g JP Poria Sclerotium 4.0 g JP Moutan Bark 4.0 g JP Peach Kernel 4.0 g JP Peony Root 4.0 g
Inactive ingredients	JP Magnesium Stearate, JP Talc, JP Carmellose Calcium, JP Light Anhydrous Silicic Acid, JP Lactose Hydrate, JP Microcrystalline Cellulose, Magnesium Hydroxide-Aluminium Hydroxide Co-Precipitate

(JP: The Japanese Pharmacopoeia)

3.2 Product Description

Dosage form	Uncoated tablet		
Color	Light brown		
Odor	Practically none or slightly characteristic odor		
Taste	Slightly bitter		
Appearance	Surface	Back	Side
			
Diameter	9.2 mm		
Thickness	4.6 mm		
Mass	330 mg		
ID code	EKT-25		

4. INDICATIONS

The following symptoms in patients who are relatively physically strong and sometimes have complaint of lower abdominal pain, shoulder muscle stiffness, dull headache, dizziness, hot flashes, and cold feet:
Menstrual irregularity, menstrual abnormality, menstrual pain, climacteric disturbance, menopausal and female climacteric states, shoulder muscle stiffness, dizziness, dull headache, bruise, chilblains, hyperpigmentation

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.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 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.Peach Kernel and 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.

11.1 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.

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, Pruritus, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, 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

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