

Disclaimer

This English translation is prepared by Marketing Authorization Holder.

The Japanese language package insert is the official document, and this translation is provided solely as a reference material. In the case of any discrepancy between the two versions, the original Japanese version prevails.

The provider of this translation shall not be responsible for any damage that may be attributed to the use of the translation.

This translation shall not be reproduced, reprinted or used for profit.

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)

Standard Commodity Classification No. of Japan	
875200	
Approval No.	21900AMX00641000
Date of Initial Marketing in Japan	Dec 1987

Kampo product

## Kracie Hangekobokuto Extract Tablets

Storage : Store at room temperature  
Shelf Life : 3 years

EKT-16




### 3. COMPOSITION AND PRODUCT DESCRIPTION

#### 3.1 Composition

Brand name	Kracie Hangekobokuto Extract Tablets		
Active ingredients	The daily dose of this product (12 tablets) contains 1,500 mg of JP Hangekobokuto extract, derived from a mixture of the following crude drugs.		
	JP Pinellia Tuber	6.0 g	
	JP Poria Sclerotium	5.0 g	
	JP Magnolia Bark	3.0 g	
	JP Perilla Herb	2.0 g	
	JP Ginger	1.3 g	
Inactive ingredients	JP Povidone, JP Synthetic Aluminum Silicate, JP Carmellose Calcium, JP Magnesium Stearate, JP Microcrystalline Cellulose		

(JP: The Japanese Pharmacopoeia)

#### 3.2 Product Description

Dosage form	Uncoated tablet			
Color	Light brown to brown			
Odor	Characteristic odor			
Taste	Slightly sweet and bitter			
Appearance	Surface	Back	Side	
				
	Diameter	9 mm		
	Thickness	5.0 mm		
Mass	300 mg			
ID code	EKT-16			

### 4. INDICATIONS

The following symptoms in patients with depressed feeling, feeling of a foreign body in the throat or esophagus, sometimes accompanied by palpitations, dizziness, nausea, etc.:

Anxiety neurosis, neurotic gastritis, nausea and vomiting of pregnancy (NVP), coughing, hoarseness

### 6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 12 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

#### 9.5 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.
Liver	Hepatic function abnormal (increased AST, ALT, 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

168 tablets (4 tablets × 3 packets × 14 sheets) [sachets]

1,764 tablets (4 tablets × 3 packets × 147 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