Kracie

Oct 2023 (1st version)

| Standard Commodity Classification No. of Japan |
|---|
| 875200 |

| Approval No. | 21900AMX00644000 |
|---|---|
| Date of Initial Marketing in Japan | Dec 1987 |

Kampo product

# Kracie Shimotsuto Extract Tablets

Storage : Store at room temperature
Shelf Life : 3 years

EKT-71

## 3. COMPOSITION AND PRODUCT DESCRIPTION

### 3.1 Composition

| Brand name | Kracie Shimotsuto Extract Tablets |
|---|---|
| Active ingredients | The daily dose of this product (18 tablets) contains 3,300 mg of Shimotsuto extract powder, derived from a mixture of the following crude drugs.<br>JP Japanese Angelica Root 3.0 g<br>JP Peony Root 3.0 g<br>JP Cnidium Rhizome 3.0 g<br>JP Rehmannia Root 3.0 g |
| Inactive ingredients | JP Magnesium Stearate,<br>JP Carmellose Calcium,<br>JP Light Anhydrous Silicic Acid,<br>JP Lactose Hydrate,<br>JP Microcrystalline Cellulose,<br>Magnesium Hydroxide-Aluminium Hydroxide Co-Precipitate |

(JP: The Japanese Pharmacopoeia)

### 3.2 Product Description

| Dosage form | Uncoated tablet | | |
|---|---|---|---|
| Color | Light brown to brown | | |
| Odor | Slightly characteristic odor | | |
| Taste | Slightly sweet, bitter afterwards | | |
| Appearance | Surface | Back | Side |
| |  |  |  |
| Diameter | 9.2 mm | | |
| Thickness | 4.9 mm | | |
| Mass | 330 mg | | |
| ID code | EKT-71 | | |

## 4. INDICATIONS

**The following symptoms in patients with dry skin and poor complexion without gastrointestinal disorders: Recovery from fatigue after postpartum or miscarriage, menstrual irregularity, sensitivity to cold, chilblain, hyperpigmentation, menopausal and female climacteric states**

## 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 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

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 |
|---|---|
| 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

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