Kracie

Oct 2023 (1st version)

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

| Approval No. | 16100AMZ03632000 |
|---|---|
| Date of Initial Marketing in Japan | Oct 1986 |

Powerful drug
[However, this does not include 2.5g packets]

Storage : Store at room temperature
Shelf Life : 3 years

**Kampo product**

# Kracie Keishikaryojutsubuto Extract Fine Granules

KB-18 EK-18

## 3. COMPOSITION AND PRODUCT DESCRIPTION

### 3.1 Composition

| Brand name | Kracie Keishikaryojutsubuto Extract Fine Granules |
|---|---|
| Active ingredients | The daily dose of this product (7.5 g) contains 4,400 mg of Keishikaryojutsubuto extract powder, derived from a mixture of the following crude drugs.<br>JP Cinnamon Bark 4.0 g<br>JP Peony Root 4.0 g<br>JP Jujube 4.0 g<br>JP Ginger 1.0 g<br>JP Glycyrrhiza 2.0 g<br>JP Atractylodes Rhizome 4.0 g<br>JP Poria Sclerotium 4.0 g<br>JP Powdered Processed Aconite Root 0.5 g |
| Inactive ingredients | JP Magnesium Stearate,<br>JP Microcrystalline Cellulose,<br>JP Light Anhydrous Silicic Acid,<br>JP Lactose Hydrate,<br>Hydrated Silicon Dioxide |

(JP: The Japanese Pharmacopoeia)

### 3.2 Product Description

| Dosage form | Fine granules |
|---|---|
| Color | Light brown to brown |
| Odor | Characteristic odor |
| Taste | Slightly pungent and sweet |
| ID code | KB-18 (3.75 g per sachet)<br>EK-18 (2.5 g per sachet) |

## 4. INDICATIONS

**Arthralgia, neuralgia**

## 6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 7.5 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** Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc. [See Sections 10.2, 11.1.1, 11.1.2.]

**8.3** 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.

### 9.5 Pregnant Women

It is not recommended to administer this product to pregnant women or women who may possibly be pregnant. Adverse reactions of Powdered Processed Aconite Root contained in this product 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.

## 10. INTERACTIONS

### 10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)

| Drugs | Signs, Symptoms, and Treatment | Mechanism and Risk Factors |
|---|---|---|
| Glycyrrhiza-containing preparations<br>Shakuyakukanzoto<br>Hochuekkito<br>Yokukansan, etc.<br>Preparations containing glycyrrhizic acid and its salts<br>Monoammonium Glycyrrhizinate/Glycine/L-cysteine<br>Monoammonium Glycyrrhizinate/Glycine/DL-Methionine combination tablets, etc.<br>[See Sections 8.2, 11.1.1, 11.1.2] | Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur. | Since glycyrrhizic acid has an accelerating effect on potassium excretion in the renal tubules, an acceleration of decrease in the serum potassium level has been suggested. |

## 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 Pseudoaldosteronism (frequency unknown)**

Pseudoaldosteronism such as hypokalaemia, blood pressure increased, retention of sodium/body fluid, edema, and body weight gain may occur. Patients should be carefully monitored (e.g., measurement of serum potassium levels), and if any abnormalities are observed, administration should be discontinued, and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

**11.1.2 Myopathy (frequency unknown)**

Myopathy may occur as a result of hypokalaemia. Patients should be carefully monitored, and if any abnormalities such as feelings of weakness, muscle cramp in extremities, or paralysis are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

**11.2 Other Adverse Reactions**

| | Frequency unknown |
|---|---|
| Hypersensitivity | Rash, Redness, Pruritus, etc. |
| Other | Palpitations, Hot flushes, Numbness of the tongue, Nausea, 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-18)
3.75 g × 28 packets [sachets]
3.75 g × 168 packets [sachets]
(EK-18)
2.5 g × 42 packets [sachets]
2.5 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