Kracie
Oct 2023 (1st version)

| Standard Commodity Classification Number of Japan |
|---|
| 875200 |

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|---|---|
| Approval No. | 16100AMZ03859000 |
| Date of Initial Marketing in Japan | Nov 1986 |

Kampo product

# TAIKODO no Kyukichoketsuin Extract Granules

Storage : Store at room temperature
Shelf Life : 3 years

EK-230

## 3. COMPOSITION AND PRODUCT DESCRIPTION

### 3.1 Composition

| Brand name | TAIKODO no Kyukichoketsuin Extract Granules |
|---|---|
| Active ingredients | The daily dose of this product (6.0 g) contains 4,580 mg of Kyukichoketsuin extract powder, derived from a mixture of the following crude drugs.<br>JP Japanese Angelica Root 2.0 g<br>JP Cnidium Rhizome 2.0 g<br>JP Rehmannia Root 2.0 g<br>JP Atractylodes Rhizome 2.0 g<br>JP Poria Sclerotium 2.0 g<br>JP Citrus Unshiu Peel 2.0 g<br>JP Cyperus Rhizome 2.0 g<br>JP Moutan Bark 2.0 g<br>JP Jujube 1.5 g<br>JP Ginger 1.0 g<br>JP Glycyrrhiza 1.0 g<br>JP Lindera Root 2.0 g<br>JP Leonurus Herb 1.5 g |
| Inactive ingredients | JP Lactose Hydrate, JP Magnesium Stearate |

(JP: The Japanese Pharmacopoeia)

### 3.2 Product Description

| Dosage form | Granules |
|---|---|
| Color | Light brown to grayish brown |
| Odor | Characteristic odor |
| Taste | Slightly bittersweet |
| ID code | EK-230 |

## 4. INDICATIONS

**Postpartum neurotic disorder, decline in physical strength, and menstrual irregularity**

## 6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6.0 g daily in 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.

## 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

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.

### 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.

## 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 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 |
|---|---|
| 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

2.0 g × 42 packets [sachets]
2.0 g × 294 packets [sachets]
500 g [bottle]

## 26. MARKETING AUTHORIZATION HOLDER, etc.

**26.1 Manufactured and Distributed by:**

**Taikoseido Pharmaceutical Co., Ltd.**
1-27 Azumadori 2-Chome, Chuo-ku, Kobe-shi, Hyogo 651-0076,Japan

**26.2 Distributed by:**

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