Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Approval No.	21900AMX00635000
Date of Initial Marketing in Japan	Oct 1986

Kampo product

Kracie Tokakujokito Extract Tablets

Storage : Store at room temperature
Shelf Life : 3 years

EKT-61

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Tokakujokito Extract Tablets
Active ingredients	The daily dose of this product (18 tablets) contains 2,200 mg of JP Tokakujokito extract, derived from a mixture of the above crude drugs. JP Peach Kernel 5.0 g JP Cinnamon Bark 4.0 g JP Rhubarb 3.0 g JP Glycyrrhiza 1.5 g JP Anhydrous Sodium Sulfate 1.0 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 to brown		
Odor	Practically none or slightly characteristic odor		
Taste	Salty at first, slightly sweet afterwards		
Appearance	Surface	Back	Side
			
Diameter	9.2 mm		
Thickness	4.6 mm		
Mass	330 mg		
ID code	EKT-61		

4. INDICATIONS

The following symptoms in patients who are relatively physically strong and tend to have hot flushes and constipated:
Menstrual irregularity, dysmenorrhea, menstrual and postpartum mental anxiety, low back pain, constipation, concomitant symptoms of hypertension (headache, dizziness, and shoulder muscle stiffness)

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 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 Rhubarb.

8.4 Since there are individual differences in the cathartic action of Rhubarb, caution should be exercised with respect to dosage and administration.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with diarrhea, loose stools
These symptoms may be aggravated.

9.1.2 Patients with an extremely weak gastrointestinal tract
Anorexia, epigastric distress, abdominal pain, diarrhea, etc. may occur.

9.1.3 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. Rhubarb (uterotonic action and congestive action on pelvic organs), Anhydrous Sodium Sulfate (uterotonic action), and Peach Kernel 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. Anthraquinone derivatives in Rhubarb contained in this product are excreted in breast milk and may cause diarrhea in infants.

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 Shakuyakukanzoto Hochuekkito Yokukansan, etc. Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/L-cysteine Monoammonium Glycyrrhizinate/Glycine/DL-Methionine combination tablets, etc. [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.
Gastrointestinal	Anorexia, Epigastric distress, Abdominal pain, Diarrhea, etc.

15. OTHER PRECAUTIONS

15.1 Information Based on Clinical Use

Since this product contains Anhydrous Sodium Sulfate, caution should be exercised when this product is administered continuously to patients who require dietary salt restriction.

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