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Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ03505000
Date of Initial Marketing in Japan	Oct 1986

Kampo product

Kracie Shakuyakukanzoto Extract Fine Granules

Storage : Store at room temperature
Shelf Life : 3 years

KB-68 EK-68

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)

2.1 Patients with aldosteronism [The disease and its symptoms may be aggravated.]
2.2 Patients with myopathy [The disease and its symptoms may be aggravated.]
2.3 Patients with hypokalaemia [The disease and its symptoms may be aggravated.]

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Shakuyakukanzoto Extract Fine Granules
Active ingredients	The daily dose of this product (6.0 g) contains 2,900 mg of JP Shakuyakukanzoto extract, derived from a mixture of the above crude drugs. JP Peony Root 6.0 g JP Glycyrrhiza 6.0 g
Inactive ingredients	JP Magnesium Stearate, JP Microcrystalline Cellulose, JP Lactose Hydrate, Hydrated Silicon Dioxide

(JP: The Japanese Pharmacopoeia)

3.2 Product Description

Dosage form	Fine granules
Color	Light brown
Odor	Characteristic odor
Taste	Sweet
ID code	KB-68 (3.0 g per sachet) EK-68 (2.0 g per sachet)

4. INDICATIONS

Sudden pain with muscle spasms, myalgia/arthralgia, stomach pain, abdominal pain

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6.0 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.

7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION

Use of this product should be limited to the minimum duration required for treatment.

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, 11.1.2, 11.1.4.]
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

9.5 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.

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 Hochuekkito Yokukansan Rikkunshito, etc. Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/L-cysteine Monoammonium Glycyrrhizinate/Glycine/DL-Methionine combination tablets, etc. Loop diuretics Azosemide Torasemide Furosemide, etc. Thiazide diuretics Trichlormethiazide Hydrochlorothiazide Benzylhydrochlorothiazide, etc. [See Sections 8.2, 11.1.2, 11.1.4]	Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur.	Since glycyrrhizic acid and diuretics promote potassium excretion in renal tubules, it is considered that a decrease in the serum potassium level may be promoted.

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 Interstitial pneumonia (frequency unknown)

If cough, dyspnea, pyrexia, abnormal lung sound, etc. are observed, administration of this product should be discontinued, and examinations such as chest X-ray and chest CT scan should be performed immediately, and appropriate measures such as administration of corticosteroid should be taken.

11.1.2 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]

11.1.3 Congestive heart failure, ventricular fibrillation, and ventricular tachycardia (including Torsade de Pointes) (frequency unknown)

Patients should be carefully monitored (e.g., serum potassium levels), if any abnormalities such as palpitations, shortness of breath, malaise, dizziness, or syncope are observed, administration should be discontinued and appropriate measures should be taken.

11.1.4 Myopathy, rhabdomyolysis (frequency unknown)

Since myopathy and rhabdomyolysis may occur as a result of hypokalaemia, patients should be carefully monitored, if feelings of weakness, muscle weakness, myalgia, limb muscle cramp/paralysis, increased CK, or rise of myoglobin in blood or urine are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

11.1.5 Hepatic impairment, jaundice (frequency unknown)

Hepatic impairment and/or jaundice with marked elevations of AST, ALT, Al-P, γ-GTP, etc. may occur.

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, Pruritus, etc.
Gastrointestinal	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

(KB-68)
3.0 g × 28 packets [sachets]
3.0 g × 168 packets [sachets]
(EK-68)
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:

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