Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Approval No.	16100AMZ03574000
Date of Initial Marketing in Japan	Oct 1986

Kampo product

Kracie Bofutsusyosan ryo Extract Fine Granules

Storage : Store at room temperature
Shelf Life : 3 years

KB-62 EK-62

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Bofutsusyosan ryo Extract Fine Granules	
Active ingredients	The daily dose of this product (7.5 g) contains 5,700 mg of JP Bofutsusyosan extract, derived from a mixture of the following crude drugs.	
	JP Japanese Angelica Root	1.2 g
	JP Peony Root	1.2 g
	JP Cnidium Rhizome	1.2 g
	JP Gardenia Fruit	1.2 g
	JP Forsythia Fruit	1.2 g
	JP Mentha Herb	1.2 g
	JP Ginger	0.4 g
	JP Schizonepeta Spike	1.2 g
	JP Saposhnikovia Root and Rhizome	1.2 g
	JP Ephedra Herb	1.2 g
	JP Rhubarb	1.5 g
	JP Atractylodes Rhizome	2.0 g
	JP Platycodon Root	2.0 g
	JP Scutellaria Root	2.0 g
	JP Glycyrrhiza	2.0 g
	JP Gypsum	2.0 g
	JP Aluminum Silicate Hydrate with Silicon Dioxide	3.0 g
	JP Anhydrous Sodium Sulfate	0.75 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 yellow-brown to brown
Odor	Characteristic odor
Taste	Slightly sweet and astringent
ID code	KB-62 (3.75 g per sachet) EK-62 (2.5 g per sachet)

4. INDICATIONS

The following symptoms in patients who have excess subcutaneous fat in the abdomen and tend to be constipated:
Concomitant symptoms of hypertension (palpitations, shoulder muscle stiffness, hot flushes), obesity, swelling, constipation

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, 11.1.2, 11.1.3.]

8.3 Prolonged administration of preparations containing Gardenia Fruit (for more than 5 years in most cases) may cause mesenteric phlebosclerosis with pigmentation, edema, erosion, ulceration, and stenosis of the colon. In the case of long-term administration, periodic examinations such as CT and colonoscopy are recommended.[See Section 11.1.5]

8.4 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.

8.5 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 a weak gastrointestinal tract
Anorexia, epigastric distress, nausea, vomiting, abdominal pain, loose stools, diarrhea, etc. may occur.

9.1.3 Patients with anorexia, nausea, or vomiting
These symptoms may be aggravated.

9.1.4 Patients in a period of weakness after disease or with extremely weakened constitution
Adverse reactions are likely to occur, and the symptoms may be aggravated.

9.1.5 Patients with a significant sweating tendency
Excessive sweating, systemic weakness, etc. may occur.

9.1.6 Patients with cardiovascular disorders, including angina pectoris or myocardial infarction, or patients with a history of such disorders
The disease and its symptoms may be aggravated.

9.1.7 Patients with severe hypertension
The disease and its symptoms may be aggravated.

9.1.8 Patients with urination impaired
The disease and its symptoms may be aggravated.

9.1.9 Patients with hyperthyroidism
The disease and its symptoms may be aggravated.

9.2 Patients with Renal Impairment

9.2.1 Patients with severe renal disorder
The disease and its 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) and Anhydrous Sodium Sulfate (uterotonic action) 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
Ephedra Herb-containing preparations Kakkonto Shoseiryuto Maoto, etc. Ephedrine-containing preparations Ephedrine Hydrochloride dl-Methyl Ephedrine Hydrochloride Fexofenadine Hydrochloride/Pseudoephedrine Hydrochloride, etc. Monoamine Oxidase (MAO) inhibitors Selegiline Hydrochloride Rasagiline Mesilate, etc. Thyroid gland preparations Thyroxine Liothyronine, etc. Catecholamine preparations Adrenaline Isoprenaline, etc. Xanthine preparations Theophylline Diprophylline, etc.	Since insomnia, excessive sweating, tachycardia, palpitation, systemic weakness, mental excitement, etc. are likely to occur, this product should be administered with care by reducing the dosage, etc.	The sympathomimetic effect may be enhanced.
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, 11.1.2, 11.1.3]	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 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. In addition, patients should be advised to discontinue administration of this product and contact the physician immediately if cough, dyspnea, or pyrexia, etc. occur.

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 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]

11.1.4 Hepatic impairment, jaundice (frequency unknown)

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

11.1.5 Mesenteric phlebosclerosis (frequency unknown)

Mesenteric phlebosclerosis may occur with long-term administration of this product. If abdominal pain, diarrhea, constipation, abdominal distension, etc. are repeatedly observed, or if fecal occult blood test is positive, administration should be discontinued, and examinations such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases. [See Section 8.3.]

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Pruritus, etc.
Autonomic	Insomnia, Excessive sweating, Tachycardia, Palpitations, Systemic weakness, Mental excitement, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Loose stools, Diarrhea, etc.
Urinary	Urination impaired, 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

(KB-62)
3.75 g × 28 packets [sachets]
3.75 g × 168 packets [sachets]
(EK-62)
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