

Storage: Store at room temperature

Shelf Life:3 years

Kampo product

Approval No.	16100AMZ03960000
Date of Initial Marketing in Japan	October 1986

N62

Kotaro Bofutsushosan Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Bofutsushosan Extract Fine Granules
Active ingredient	9.0g of Kotaro Bofutsushosan Extract Fine Granules contains 6.0g of the dried extract of the following mixed crude drugs.
	JP Japanese Angelica Root..... 1.2g
	JP Peony Root..... 1.2g
	JP Cnidium Rhizome..... 1.2g
	JP Gardenia Fruit 1.2g
	JP Forsythia Fruit 1.2g
	JP Mentha Herb..... 1.2g
	JP Ginger 0.3g
	JP Schizonepeta Spike 1.2g
	JP Saposhnikovia Root and Rhizome..... 1.2g
	JP Ephedra Herb..... 1.2g
	JP Rhubarb..... 1.5g
	JP Anhydrous Sodium Sulfate 0.7g
	JP Atractylodes Rhizome 2.0g
	JP Platycodon Root 2.0g
	JP Scutellaria Root..... 2.0g
	JP Glycyrrhiza..... 2.0g
JP Gypsum..... 2.0g	
JP Aluminum Silicate Hydrate with Silicon Dioxide 3.0g	
(JP: Japanese Pharmacopoeia)	
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

3.2 Product Description

Dosage form	Fine granules
Color	Light brown to brown
Taste	Slightly bitter
Odor	Characteristic odor
ID code	N62

4. INDICATIONS

The following symptoms in patients with the conditions below: constipation due to fatty constitution and decreased urine output. Chronic constipation, gastric hyperacidity, kidney diseases, heart failure, arteriosclerosis, hypertension, cerebral hemorrhage, shoulder muscle stiffness associated with these conditions.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 9.0g daily in 2 or 3 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 phleboscrosis 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 an extremely 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 such as 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 decrease 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
<p>Ephedra Herb-containing preparations Kakkonto Shoseiryuto Maoto, etc.</p> <p>Ephedrine-containing preparations Ephedrine Hydrochloride dl-Methyl Ephedrine Hydrochloride Fexofenadine Hydrochloride/Pseudoephedrine Hydrochloride, etc.</p> <p>Monoamine Oxidase (MAO) inhibitors Selegiline Hydrochloride Rasagiline Mesilate, etc.</p> <p>Thyroid gland preparations Thyroxine Liothyronine, etc.</p> <p>Catecholamine preparations Adrenaline Isoprenaline, etc.</p> <p>Xanthine preparations Theophylline Diprophylline, etc.</p>	<p>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.</p>	<p>The sympathomimetic effect may be enhanced.</p>
<p>Glycyrrhiza-containing preparations Shakuyakukanzoto Hochuekkito Yokukansan, etc.</p> <p>Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/L-cysteine Monoammonium Glycyrrhizinate/Glycine/DL-Methionine combination tablets, etc.</p> <p>[See Sections 8.2, 11.1.2, 11.1.3]</p>	<p>Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur.</p>	<p>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.</p>

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 phleboscrosis (frequency unknown)

Mesenteric phleboscrosis 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

- 500g [bottle, loose]
3.0g x 42 packets [sachets]
3.0g x 168 packets [sachets]

24. REFERENCE REQUEST AND CONTACT INFORMATION

Pharmaceutical Division, Kotaro Pharmaceutical Co., Ltd.
5-23, Nakatsu 2-chome, Kita-ku, Osaka 531-0071, Japan

26. MARKETING AUTHORIZATION HOLDER, etc.

- 26.1 Marketing Authorization Holder
Kotaro Pharmaceutical Co., Ltd.
5-23, Nakatsu 2-chome, Kita-ku, Osaka 531-0071, Japan