ID Code	SG-62

October 2005
(1st version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

OHSUGI Bofutsushosan Extract Granules G

(Bofutsushosan)

Storage: Store at room temperature. See the section "PRECAUTIONS FOR HANDLING" Expiration date: The expiration date is specified on the container or the outer package

Approval No.	(61AM) 3890
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

DESCRIPTION

(1) The daily dose of this product, 9.0g, contains 5.2g of the dried extract (Bofutsushosan extract) from the following mixed crude drugs.

JP Japanese Angelica Root ---------- 1.2 g
JP Ephedra Herb ---------- 1.2 g
JP Peony Root ---------- 1.2 g
JP Rhubarb ---------- 1.5 g
JP Cnidium Rhizome ---------- 1.2 g
Sodium Sulfate Hydrate ---------- 0.7 g
JP Gardenia Fruit ---------- 1.2 g
JP Atractylodes Rhizome ---------- 2.0 g
JP Forsythia Fruit ---------- 1.2 g
JP Platycodon Root ---------- 2.0 g
JP Mentha Herb ---------- 1.2 g
JP Scutellaria Root ---------- 2.0 g
JP Ginger ---------- 0.3 g
JP Gypsum ---------- 2.0 g
JP Schizonepeta Spike ---------- 1.2 g
JP Glycyrrhiza ---------- 2.0 g
JP Saposhnikovia Root and Rhizome---------- 1.2 g
JP Aluminum Silicate Hydrate with Silicon Dioxide ------- 3.0 g

(JP: The Japanese Pharmacopeia)

The inactive ingredients contained are Lactose Hydrate, Corn Starch and Magnesium Stearate.

(2) This product is light grayish and dark brown to light grayish brown-colored granules, smells uniquely, and tastes sweet initially and then slightly bitter.
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INDICATIONS

The following symptoms of those patients with thick subcutaneous fat in the abdomen and a tendency to constipation:
Accessory symptoms associated with hypertension (palpitations, shoulder stiffness, and hot flushes), obesity, swelling, and constipation

DOSAGE AND ADMINISTRATION

The usual adult dose is 9.0 g/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

PRECAUTIONS

(1) Careful Administration (Bofutsushosan should be administered with care in the following patients.)

1) Patient with diarrhea or soft stool [These symptoms may be aggravated]
2) Patients with a weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, abdominal pain, soft feces, diarrhea, etc. may occur.]
3) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated]
4) Patients in a period of weakness after disease or with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]
5) Patients showing a remarkable tendency of sweating [Excess sweating and/or generalized weakness may occur.]
6) Patients with cardiovascular disorders including angina pectoris and myocardial infarction, etc. or those with a history of such disorders.
7) Patients with severe hypertension
8) Patients with severe renal dysfunction
9) Patients with dysuria
10) Patients with hyperthyroidism

[6)- 10): These disease and symptoms may be aggravated.]

(2) Important Precautions

1) When this product is used, the patient's "SHO" (constitution/symptoms) should be taken into account. The patient's progress should be carefully monitored, and if no improvement in symptoms/findings is observed, continuous treatment should be avoided.
2) Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc., and if any abnormality is observed, administration should be discontinued.
3) When this product is coadministered with other Kampo-products (Japanese traditional herbal medicines), etc., attention should be paid to the duplication of the contained crude drugs.Special caution should be exercised when this product is coadministered with preparations containing Rhubarb.
4) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

(3) Drug Interactions

Precautions for coadministration (Bofutsushosan should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Ephedra Herb (2) Preparations containing ephedrine-related compounds (3) Monoamine oxidase (MAO) inhibitors (4) Thyroid preparations Thyroxine Liothyroxine (5) Catecholamine preparations Adrenaline Isoprenaline (6) Xanthine preparations Theophylline Diprophylline	Insomnia, excessive sweating, tachycardia, palpitation, general weakness, mental excitation, etc. are likely to occur. In such cases, this product should be administered with care by measures such as reducing the dosage.	An enhancement of the sympathetic nerve-stimulating action has been suggested.
(7) Preparations containing Glycyrrhiza (8) Preparations containing glycyrrhizinic acid or glycyrrhizinates	Pseudoaldosteronism is likely to occur, Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section “Clinically significant adverse reactions”.)	Since glycyrrhizinic acid has an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested.

(4) Adverse Reactions

This product has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

1) Clinically significant adverse reactions

① **Interstitial Pneumonia**: If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of this product should be discontinued, and examination such as chest X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones should be taken. Besides, the patient should be advised to discontinue this product immediately and to make contact with the physician in the event of fever, cough, dyspnea, etc.

② **Pseudoaldosteronism**: Pseudoaldosteronism such as hypokalemia, increased blood pressure, retention of sodium/body fluid, edema, increased body weight, etc. may occur. The patient should be carefully monitored (measurement of serum potassium level, etc.), and if any abnormality is observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

③ **Myopathy**: Myopathy may occur as a result of hypokalemia. The patient should be carefully monitored, and if any abnormality such as weakness, convulsion/paralysis of limbs, etc. are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

④ **Hepatic dysfunction and jaundice**: Hepatic dysfunction, with remarkable elevation of AST(GOT), ALT(GPT), Al-P and γ - GTP level, and/ or jaundice may occur. The patient should be carefully monitored for abnormal findings. Administration should be discontinued and appropriate therapeutic measures should be taken, if abnormalities are observed.

2) Other adverse reactions

	Incidence Unknown
Hypersensitivity Note 1)	Rash, Pruritus, etc.
Autonomic nervous system	Insomnia, Excess sweating, Tachycardia, Palpitation, General weakness, Mental excitation, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Soft feces, Diarrhea, etc.
Urinary	Urination disorder, etc.

Note 1) If such symptoms are observed, administration should be discontinued.

(5) Use in the Elderly

Because elderly patients often have reduced physiological function,careful supervision and measures such as reducing the dose are recommended.

(6) Use during Pregnancy, Delivery or Lactation

1) Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [Rhubarb (uterotonic action and congestive action on the intrapelvic organs), anhydrous Mirabilitum (uterotonic action), and Peach Kernel contained in this product may cause premature birth or abortion.]

2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in the breast milk and induce diarrhea in nursed infants.]

(7) Pediatric Use

The safety of this product in children has not been established. [Insufficient clinical data]

(8) Other

Since this product contains Mirabilitum, caution should be exercised when continuous treatment with this product is given to patients who need limited salt-intake therapeutically.

PRECAUTIONS FOR HANDLING

- Store at dry and cool place, protected from direct sunlight.
- Since this product contains natural crude drugs, some differences may be noted in the color or taste, etc. However, there is no change in the effect.

PACKAGING

500g
882g (3.0g x 294 packets)
252g (3.0g x 84 packets)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., Ltd.
1-8-6, Yamasaka, Higashisumiyoshi-ku, Osaka 546-0035
050-3776-0358