Revised: February 2018 (9th version)

Standard Commodity Classification No. of Japan
875200

■62■

- Kampo-preparation-

TSUMURA Bofutsushosan Extract Granules for Ethical Use

Storage
Store in light-resistant, air-tight containers.

Expiration date
Use before the expiration date indicated on the container and the outer package.

Approval No.	(61AM)1172
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

DESCRIPTION

Composition	7.5 g of TSUMURA Bofutsushosan extract granules (hereafter TJ-62) contains 4.5 g of a dried extract of the following mixed crude drugs. JP Alminum Silicate Hydrate with Silicon Dioxide …….. 3.0 g JP Scutellaria Root ..... 2.0 g JP Glycyrrhiza ..... 2.0 g JP Platycodon Root ..... 2.0 g JP Gypsum ..... 2.0 g JP Atractylodes Rhizome ..... 2.0 g JP Rhubarb ..... 1.5 g JP Schizonepeta Spike ..... 1.2 g JP Gardenia Fruit ..... 1.2 g JP Peony Root ..... 1.2 g JP Cnidium Rhizome ..... 1.2 g JP Japanese Angelica Root ..... 1.2 g JP Mentha Herb ..... 1.2 g JP Saposhnikovia Root and Rhizome..... 1.2 g JP Ephedra Herb ..... 1.2 g JP Forsythia Fruit ..... 1.2 g JP Anhydrous Sodium Sulfate..... 0.7 g JP Ginger ..... 0.3 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Light Anhydrous Silicic Acid JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Yellow-brown
	Smell	Characteristic smell
	Taste	Slightly sweet and unique flavor
	ID code	TSUMURA/62

INDICATIONS

TJ-62 is indicated for the relief of the following symptoms of those patients with thick subcutaneous fat in the abdomen and a tendency to constipation:

Accessory symptoms associated with hypertension (palpitation, shoulder stiffness, and hot flushes), obesity, swelling, and constipation.

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 g/day orally in 2 or 3 divided doses before or between meals. The dosage may be adjusted according to the patient's age and body weight, and symptoms.

PRECAUTIONS

1. Careful administration (TJ-62 should be administered with care in the following patients.)

(1) Patients with diarrhea or soft feces [These symptoms may be aggravated.]

(2) Patients with 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 TJ-62 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 TJ-62 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) Long-term administration of a gardenia fruit-containing preparation (usually 5 years or longer) may cause mesenteric phlebosclerosis accompanied by discoloration, edema, erosion, ulceration, and stenosis of the colon. Periodical examinations such as CT scanning and colonoscopy would be desirable in cases of its long-term administration.

(4) When TJ-62 is co-administered with other Kampo-preparations (Japanese traditional herbal medicines), etc., attention should be paid to the duplication of the contained crude drugs. Special caution should be exercised when TJ-62 is co-administered with preparations containing Rhubarb.

(5) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

SHO: The term "SHO" refers to a particular pathological status of a patient evaluated by the Kampo diagnosis, and is patterned according to the patient's constitution, symptoms, etc. Kampo-preparations (Japanese traditional herbal medicines) should be used after confirmation that it is suitable for the identified "SHO" of the patient.

3. Drug Interactions

Precautions for coadministration (TJ-62 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 Liothyronine (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, TJ-62 should be administered with care by measures such as reducing the dosage.	An enhancement of the sympathetic nerve-stimulating action has been suggested.
(1) Preparations containing Glycyrrhiza (2) Preparations containing glycyrrhizinic acid or glycyrrhizinates (3) Loop diuretics Furosemide Etacrynic acid (4) Thiazide diuretics Trichlormethiazide	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 and diuretics have 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

TJ-62 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 TJ-62 should be discontinued, and examinations such as X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken. Besides, the patient should be advised to discontinue TJ-62 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 and/or jaundice with remarkable elevation of AST (GOT), ALT (GPT), Al-P and γ-GTP or other symptoms 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.

5) Mesenteric phlebosclerosis: Mesenteric phlebosclerosis may occur with long-term administration. If symptoms such as abdominal pain, diarrhea, constipation, and abdominal distension repeatedly occur, or if the patient tests positive for fecal occult blood, administration should be discontinued. At the same time, tests such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases.

(2)Other adverse reactions

	Incidence unknown
Hypersensitivity Note 1)	Rash, Urticaria, etc.
Autonomic	Insomnia, Excess sweating, Tachycardia, Palpitation, Generalized 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 TJ-62 in pregnant women, women who may possibly be pregnant is not recommended. [Rhubarb (uterotonic action and congestive action on the intrapelvic organs), Anhydrous Sodium Sulfate (uterotonic action) contained in TJ-62 may cause premature birth or abortion.]

(2) TJ-62 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-62 may be excreted in breast milk and induce diarrhea in nursing infants.]

7. Pediatric Use

The safety of TJ-62 in children has not been established. [Insufficient clinical data.]

8. Other Precautions

TJ-62 contains Anhydrous Sodium Sulfate. Caution should be exercised when continuous treatment with TJ-62 is given to patients who need limited salt-intake therapeutically.

PHARMACOLOGY

1. Actions on obesity

Administration of a food containing Bofutsushosan to MSG-obese mice inhibited weight gain[1)].

2. Mechanism of action

Bofutsushosan was suggested to exhibit the pharmacological effects by the following mechanisms of action.

Activation of brown adipose tissues

Administration of a food containing Bofutsushosan to MSG-obese mice activated brown adipose tissues[1)].

PACKAGING

Bottles of 500 g and boxes of 5 kg (500 g × 10 bottles)
2.5 g × 42 packets
2.5 g × 189 packets

REFERENCES

1) Yoshida, T. et al. Int. J. Obes. 1995, 19, p.717.

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Consumer Information Services Center
Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan
TEL:0120-329970 FAX03-5574-6610

Manufactured and Distributed by:

Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan