

Information sheet for customer

Tsumura-Kampo Bofutsusyosan[防風通聖散] Extract Granules

【Category 2 OTC medicines】

INDICATIONS

Following symptoms in persons with substantial physical strength who have enough abdominal subcutaneous fat and a tendency to constipation:

Palpitations, stiff shoulder, hot flashes, edema and constipation associated with hypertension and obesity, empyema (sinusitis), eczema/dermatitis, Pimple (acne), and obesity.

! CAUTION FOR USE

●To be avoided

Failure to observe the following may result in the symptoms worsening or the occurrence of adverse reactions/accidents.

1. This medication should not be used in combination with the following medications:

Other cathartic agents.

2. Women who are nursing should not take this medicine. If those women take it, avoid breast feeding.

●Who should seek consultation

1. The following persons should consult a physician, pharmacist, or registered distributor before taking this medicine.

- (1) Persons undergoing medical treatment from a physician.
- (2) Pregnant women or women suspected of being pregnant.
- (3) Persons who is physically weak(declining of strength or constitutional weakness)
- (4) Persons with weak stomach and intestine who have a tendency to diarrhea, diarrhea with severe abdominal pain.
- (5) Persons with excessive sweating.
- (6) Elderly persons.
- (7) Persons who have experienced rash, redness, itching, etc. due to medicines or something.
- (8) Persons with the following symptoms: edema, urination difficulty.
- (9) Persons diagnosed as having the following: hypertension, heart disease, kidney disease, thyroid disease.

2. The following symptoms may be adverse reactions to this medication. If any of these symptoms occur, stop taking this medicine immediately and consult a physician, pharmacist, or registered distributor. Take the instruction leaflet with you.

Related areas	Symptoms
Skin	Rash, redness, itching
Gastrointestinal system	Nausea, vomiting, loss of appetite, gastric distress, feeling of enlarged abdomen, diarrhea with severe abdominal pain, abdominal pain
Neuropsychiatric system	Dizziness.
Others	Sweating, palpitations, edema, headache.

In very rare cases the following serious symptoms may occur. In this case, consult a physician immediately.

Symptoms' name	Symptoms
Interstitial pneumonia	When go upstairs or exert yourself too much, symptoms such as shortness of breath, breathing difficulties, dry cough, and fever will appear. They will appear suddenly and persist.
Pseudohyperaldosteronism, myopathy	In addition to listlessness, stretched feeling, and stiffness of hands and feet, feeling of weakness and muscular pain will appear and gradually worsen.
Hepatic function failure	Following symptoms appear: fever, itching, rash, jaundice (yellowing of skin and white of eyes), brown urine, whole-body tiredness, loss of appetite.
Mesenteric phlebosclerosis	Long-term use of this medicine may cause repetitive appearance of following symptoms: abdominal pain, diarrhea, constipation, abdominal bloating.



3. A following symptom may appear after taking this medicine. If the symptom continues or worsen, consult a physician, pharmacist or registered distributor. Take this leaflet with you: diarrhea, constipation.
4. Stop taking this medicine and consult a physician, pharmacist or registered distributor if symptoms do not improve after taking this medicine for about 1 month (1 week if you take this medicine for constipation). Take this leaflet with you.
5. If you take this medicine regularly for a long periods, consult a physician, pharmacist or registered distributor.

DOSAGE

Take the following dosages with water or warm water before a meal.

Age	One dosage	Daily dosage
15 years and over	1 packet (1.875 g)	2 times a day
7-14 years	2/3 packet	
4-6 years	1/2 packet	
2-3 years	1/3 packet	
Less than 2 years	Do not use	

[Cautions] This medication should be given to children only under adult supervision

INGREDIENTS

2 packets (3.75 g) of this medicine contain 2.25 g of Bofutsusyosan extract of the following mixed crude drugs;

JP Alminum Silicate Hydrate with Silicon Dioxide	1.5 g
JP Scutellaria Root	1.0 g
JP Glycyrrhiza	1.0 g
JP Platycodon Root	1.0 g
JP Gypsum	1.0 g
JP Atractylodes Rhizome	1.0 g
JP Rhubarb	0.75 g
JP Schizonepeta Spike	0.6 g
JP Gardenia Fruit	0.6 g
JP Peony Root	0.6 g
JP Cnidium Rhizome	0.6 g
JP Japanese Angelica Root	0.6 g
JP Mentha Herb	0.6 g
JP Saposhnikovia Root	0.6 g
JP Ephedra Herb	0.6 g
JP Forsythia Fruit	0.6 g
JP Anhydrous Sodium Sulfate	0.35 g
JP Ginger	0.15 g

(JP: The Japanese Pharmacopoeia)

Inactive ingredients: JP Magnesium Stearate, JP Lactose Hydrate, Sucrose Esters of Fatty Acids.

PRECAUTIONS FOR STORAGE AND HANDLING

- (1) Store in a cool, dry place free from direct sunlight.
- (2) Keep all medication out of the reach of children.
- (3) When you take this medicine in divided dose, fold over the opened edge of the packet and store it. The remaining medicine should be taken within 2 days.
- (4) Since the medicine contains crude drugs, the granules color may vary for individual products, however this has no influence on the efficacy of this medicine.
- (5) Do not take this medicine after the expiration date.

Production of this product has been approved for domestic sales in accordance with the Pharmaceutical Affairs Law of Japan.



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