

Revised: June 2016 (4th version)

Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

Powerful drug **SANWA Bushirichuto Extract Fine Granules**

&lt;bushirichuto&gt;

S-09

This product is easy to take, fine granules made from the extract of "bushirichuto" listed in "JKISHIHO".

**Storage. Precautions for handling**

Since this product is hygroscopic property, keep a container tightly closed in a cool place away from direct rays after use.

**Expiration date**

Use before the expiration date indicated on the label or the package.

Approval No.	(61AM)3614
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	November 1986

**CONTRAINDICATIONS (Bushirichuto is contraindicated in the following patients.)**

1. Patients with aldosteronism
  2. Patients with myopathy
  3. Patients with hypokalemia
- [1-3: These diseases or symptoms may be aggravated.]

**DESCRIPTION****Composition**

4.5g/day of this product contains 2.8g of a dried Bushirichuto extract of the following mixed crude drugs.

JP Ginseng.....	3.0g
JP Glycyrrhiza.....	3.0g
JP Atractylodes Rhizome.....	3.0g
JP Processed Ginger.....	3.0g
JP Processed Aconite Root.....	1.0g

(JP: The Japanese Pharmacopoeia)

It also contains Lactose Hydrate, Corn Starch, Microcrystalline Cellulose, Partly Pregelatinized Starch, Light Anhydrous Silicic Acid as inactive ingredients.

**Product Description**

This product is fine granules, brown color, it has characteristic smell, and it tastes pungent and a little sweet.

ID code: S-09

**INDICATIONS**

The following symptoms of those patients with gastrointestinal weakness, a bad complexion, a face without vitality, high urine output, cold feeling in the extremities, tendency to diarrhea, frequent nausea, dizziness, dull headache and stomachache:

Chronic gastrointestinal catarrh and gastric atony

**DOSAGE AND ADMINISTRATION**

The usual adult dose is 4.5g/day orally in 3 divided doses before or between meals. The dosage may be adjusted according to the patient's age and symptoms.

**PRECAUTIONS****1. Careful Administration (Bushirichuto should be administered with care in the following patients.)**

- (1) Patients with strong constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]
- (2) Patients with sensitivity to heat, a tendency towards hot flush and red face. [Palpitation, hot flush, numbness of the tongue, nausea, etc. may occur.]

**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-preparations (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 Aconite Root.
- 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 (Bushirichuto should be administered with care when coadministered with the following drugs.)**

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Glycyrrhiza	Pseudoaldosteronism is likely to occur.	Since glycyrrhizic 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.
(2) Preparations containing glycyrrhizic acid or glycyrrhizinates	Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".)	
(3) Loop diuretics Furosemide Etacrynic acid		
(4) Thiazide diuretics Trichlormethiazide		

#### 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) **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.

2) **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.

##### (2) Other adverse reactions

	Incidence unknown
<b>Hypersensitivity</b> <sup>Note1)</sup>	Rash, Urticaria, etc.
<b>Others</b>	Palpitation, Hot flush, Numbness of the tongue, Nausea, etc.

Note1) 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

Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [ Adverse reactions due to Processed Aconite Root contained in this product are likely to occur.]

#### 7. Pediatric Use

This product should be administered with care in children.

[This product contains Processed Aconite Root.]

#### PACKAGING

Bottles of 500g

1.5g x 300 packets

#### Manufactured and Distributed by:

Sanwa Shoyaku Co., Ltd.

6-1, Hiraide-Kogyo-Danchi, Utsunomiya-city, Tochigi, 321-0905,

Japan