

Revised: April 2011 (5th version)

Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

Powerful drug **SANWA Shimbuto Extract Fine Granules**

<shimbuto>
S-02

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

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)3620
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	November 1986

DESCRIPTION**Composition**

4.5g/day of this product contains 2.4g of a dried JP Shimbuto extract of the following mixed crude drugs.

JP Poria Sclerotium.....	5.0g
JP Peony Root.....	3.0g
JP Ginger.....	1.0g
JP Atractylodes Rhizome.....	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 bitter.

ID code: S-02

INDICATIONS

The following symptoms of those patients with decreased metabolism, cold extremities and low back, severe fatigue and malaise, decreased urinary output, tendency to diarrhea, palpitation and dizziness:

Weak digestive system, chronic gastrointestinal catarrh, and chronic nephritis

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 (Shimbuto 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) 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. 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.

	Incidence unknown
Hypersensitivity ^{Note1)}	Rash, Redness, Pruritus, Urticaria, etc.
Others	Palpitation, Hot flush, Numbness of the tongue, Nausea, etc.

Note1) If such symptoms are observed, administration should be discontinued.

4. Use in the Elderly

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

5. 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.]

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6. 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