Sanwa Shoyaku Co., Ltd.

Revised: August 2008 (2nd version)

Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

SANWA Mokuboito Extract Fine Granules

<mokuboito>

S-28

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

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)3626
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 1.7g of a dried Mokuboito extract of the following mixed crude drugs.

JP Sinomenium Stem and Rhizome…… 4.0g
JP Gypsum…….10.0g
JP Cinnamon Bark…….. 2.0g
JP Ginseng…….. 2.0g
(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 a little bitter.
ID code: S-28

INDICATIONS

The following symptoms of those patients with blocked feeling in the epigastric region, dyspnea with asthma, tendency to edema, decreased urine volume and dry mouth, etc.:

Heart valve disease, cardiac asthma, chronic nephritis, and nephrosis

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 (Mokuboito should be administered with care in the following patients.)

Patients with weak gastrointestinal tract [Anorexia, epigastric distress, soft feces, diarrhea, 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.

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
HypersensitivityNote1)	Rash, Redness, Pruritus, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Soft feces, Diarrhea, 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

The safety of this product in pregnant women has not been established. Therefore, the product should be used in pregnant women, women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

6. Pediatric Use

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

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