Sanwa Shoyaku Co., Ltd.

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Standard Commodity Classification No. of Japan
875200

-Kampo-preparation-

Powerful drug SANWA Daibofuto Extract Fine Granules

(500g bottles only) <daibofuto>

S-06

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

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)3623
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	November 1986

DESCRIPTION

Composition

9g/day of this product contains 6.5g of a dried Daibofuto extract of the following mixed crude drugs.

JP Japanese Angelica Root……3.0g
JP Peony Root……..... 3.0g
JP Rehmannia Root…….. 3.0g
JP Astragalus Root…… 3.0g
JP Glehnia Root and Rhizome……. 3.0g
JP Eucommia Bark……3.0g
JP Atractylodes Rhizome…….....3.0g
JP Cnidium Rhizome…… 2.0g
JP Ginseng…… 1.5g
JP Notopterygium……. 1.5g
JP Achyranthes Root…… 1.5g
JP Glycyrrhiza…….. 1.5g
JP Ginger……. 0.5g
JP Jujube…….. 1.5g
JP Processed Aconite Root…….. 0.5g

(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 and a little sweet.
ID code: S-06

INDICATIONS

The following symptoms of those patients who have swollen, painful, paralyzed, and stiff joints that are hard to bend or stretch:
Articular rheumatism of the lower limbs, chronic arthritis, and gout

DOSAGE AND ADMINISTRATION

The usual adult dose is 9g/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 (Daibofuto 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.]
(3) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]
(4) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]

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 (Daibofuto should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1)Preparations containing Glycyrrhiza (2)Preparations containing glycyrrhizinic acid or glycyrrhizinates	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 has 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

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
HypersensitivityNote1)	Rash, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Diarrhea, etc.
Others	Palpitation, Hot flush, Numbness of the tongue,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. [Achyranthes Root contained in this product may cause premature birth or abortion. Besides, 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.]

8. Other Precautions

Eczema, dermatitis, etc. may be aggravated.

PACKAGING

Bottles of 500g
3g x 300 packets (This product is not powerful drug.)

Manufactured and Distributed by:

Sanwa Shoyaku Co., Ltd.
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