ID Code	SG-53

October 2005
(1st version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

OHSUGI Sokeikakketsuto Extract Granules G

(Sokeikakketsuto)

Storage: Store at room temperature. See the section "PRECAUTIONS FOR HANDLING" Expiration date: The expiration date is specified on the container or the outer package

Approval No.	(61AM) 3896
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

DESCRIPTION

(1) The daily dose of this product, 12.0g, contains 5.6g of the dried extract (Sokeikakketsuto extract) from the following mixed crude drugs.

JP Japanese Angelica Root ---------- 2 g
JP Sinomenium Stem and Rhizome ---------- 1.5 g
JP Rehmannia Root ---------- 2 g
JP Notopterygium ---------- 1.5 g
JP Atractylodes Rhizome ---------- 2 g
JP Glehnia Root and Rhizome ---------- 1.5 g
JP Cnidium Rhizome ---------- 2 g
JP Japanese Gentian ---------- 1.5 g
JP Peach Kernel ---------- 2 g
JP Ginger ---------- 0.5 g
JP Poria Sclerotium ---------- 2 g
JP Citrus Unshiu Peel ---------- 1.5 g
JP Peony Root ---------- 2.5 g
JP Angelica Dahurica Root ---------- 1 g
JP Achyranthes Root ---------- 1.5 g
JP Glycyrrhiza ---------- 1 g
JP Clematis Root ---------- 1.5 g
(JP: The Japanese Pharmacopeia)

The inactive ingredients contained are Lactose Hydrate, Corn Starch and Magnesium Stearate.

(2) This product is grayish brown-colored granules, smells slightly, and tastes lingeringly bitter.
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INDICATIONS

Arthralgia, neuralgia, low back pain, and myalgia

DOSAGE AND ADMINISTRATION

The usual adult dose is 12.0 g/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

PRECAUTIONS

(1) Careful Administration (Sokeikakketsuto should be administered with care in the following patients.)

1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]
2) 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-products (Japanese traditional herbal medicines), etc. attention should be paid to the duplication of the contained crude drugs.

(3) Drug Interactions

Precautions for coadministration (Sokeikakketsuto 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
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Diarrhea, etc.

(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 and Peach Kernel contained in this product may cause premature birth or abortion.]

(7) Pediatric Use

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

PRECAUTIONS FOR HANDLING

Store in a cool place with low humidity avoiding direct sunlight.

PACKAGING

500g
1,176g (4.0g x 294 packets)
336g (4.0g x 84 packets)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., Ltd.
1-8-6, Yamasaka, Higashisumiyoshi-ku, Osaka 546-0035
050-3776-0358