

February 2011
(2nd version)Standard Commodity Classification No. of Japan
875200

- Kampo product -

OHSUGI San'oshashinto Extract Granules G
(San'oshashinto)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) 4807
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

(1) The daily dose of this product, 3.0g, contains 1.4g of the dried extract (San'oshashinto extract) from the following mixed crude drugs.

JP Scutellaria Root ----- 3 g
JP Coptis Rhizome ----- 3 g
JP Rhubarb ----- 3 g

(JP: The Japanese Pharmacopeia)

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

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

ID Code: SG-113

INDICATIONS

The following symptoms of those patients with a comparatively strong constitution who have a slight feeling of hot flushes and have facial hot flushes, mental instability, and are likely to have constipation:

Symptoms associated with hypertension (flushing, shoulder stiffness, tinnitus, dull headache, insomnia, and anxiety), nose bleeding, hemorrhoidal bleeding, constipation, climacteric disturbance, and automatic imbalance syndrome peculiar to women resembling climacteric disturbance

DOSAGE AND ADMINISTRATION

The usual adult dose is 3.0 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 (San'oshashinto should be administered with care in the following patients.)**

- 1) Patient with diarrhea, or soft feces [These symptoms may be aggravated]
- 2) Patients with an extremely weak gastrointestinal tract [Anorexia, abdominal pain, diarrhea, etc. may occur.]
- 3) Patients with an extremely declined constitution [Adverse reactions are likely to occur, and the 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) When this product is coadministered with other Kampo-products (Japanese traditional herbal medicines), etc., attention should be paid to any duplication of the contained crude drugs. Special caution should be exercised when this product is coadministered with other products containing Rhubarb.
- 3) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

(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.

1) Clinically significant adverse reactions

- ① **Interstitial pneumonia:** If fever, cough, dyspnea, abnormal pulmonary sound, etc., are observed, administration of this product should be discontinued, and examinations such as chest X-ray or chest CT should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken.
- ② **Hepatic dysfunction and jaundice:** Hepatic dysfunction and/or jaundice with remarkable elevation of AST(GOT), ALT(GPT), Al-P and γ -GTP etc. may occur. The patient should be carefully monitored for abnormal findings. Administration should be discontinued and appropriate therapeutic measures should be taken, if abnormalities are observed

2) Other adverse reactions

	Incidence Unknown
Gastrointestinal	Anorexia, Abdominal pain, Diarrhea, etc.

(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

- 1) Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in this product may cause premature birth or abortion.]
- 2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in breast milk and induce diarrhea in nursed infants.]

(6) Pediatric Use

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

PRECAUTIONS FOR HANDLING

- Store at dry and cool place, protected from direct sunlight.
- Since this product contains natural crude drugs, some differences may be noted in the color or taste, etc. However, there is no change in the effect.

PACKAGING

500g
294g (1.0g x 294 packets)
84g (1.0g x 84 packets)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., LTD.
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050-3776-0358