

August 2009
(2nd version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

OHSUGI Shofusan Extract Granules G (Shofusan)

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
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Approval No.	(62AM) 0324
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, 7.5g, contains 4.0g of the dried extract (Shofusan extract) from the following mixed crude drugs.

JP Japanese Angelica Root -----	3 g
JP Saposhnikovia Root and Rhizome -----	2 g
JP Rehmannia Root -----	3 g
JP Akebia Stem -----	2 g
JP Gypsum -----	3 g
JP Glycyrrhiza -----	1 g
JP Anemarrhena Rhizome -----	1.5 g
Cicada Slough -----	1 g
JP Sesame -----	1.5 g
JP Sophora Root -----	1 g
JP Atractylodes Lancea Rhizome -----	2 g
JP Schizonepeta Spike -----	1 g
JP Burdock Fruit -----	2 g

(JP: The Japanese Pharmacopeia)

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

(2) This product is light grayish brown-colored granules, smells uniquely, and tastes sweet initially and then bitter.

ID Code: SG-22

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 any duplication of the contained crude drug

(3) Drug Interactions

Precautions for coadministration (Shofusan should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Glycyrrhiza	Pseudoaldosteronism is likely to occur. Besides, myopathy is likely to occur	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.
(2) Preparations containing glycyrrhizinic acid or glycyrrhizinates	resulting from hypokalemia. (Refer to the section "Clinically significant adverse reactions")	

INDICATIONS

Chronic eczema/dermatitis (oozing type)

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 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 (Shofusan should be administered with care in the following patients.)

- 1) Patients with a weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, soft stool, diarrhea, etc. may occur.]
- 2) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated]
- 3) Patients with a remarkably 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.

(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
Hypersensitivity Note 1)	Rash, Redness, Pruritus, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Soft stool, Diarrhea, etc.

Note 1) 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.

(5) Use during Pregnancy, Delivery or Lactation

The safety of this product in pregnant woman 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.

(7) Pediatric Use

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

(8) Other Precautions

Symptoms may be aggravated in dermatosis with dry affected areas.

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
735g (2.5g x 294 packets)
210g (2.5g 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