

-Kampo product-

SG-09

OHSUGI Shosaikoto
Extract Granules G

SG-09 T

OHSUGI Shosaikoto
Extract T Tablets
(Shosaikoto)

Storage : Store at room temperature

Shelf Life : 3 years

| | Approval No. | Date of Initial Marketing in Japan |
|------------|------------------|------------------------------------|
| Granules G | 16100AMZ03876000 | October 1986 |
| T Tablets | 16100AMZ04190000 | October 1986 |

1. WARNINGS

1.1 This product may cause interstitial pneumonia, which may lead to serious outcomes such as death if appropriate treatment is not applied early. Monitor the patient's condition closely, and discontinue administration of this product immediately if cough, dyspnea, pyrexia, abnormal lung sound, abnormal chest X-ray, abnormal chest CT, etc. are observed. [See Sections 2.2, 2.3, 8.4, 9.3.1-9.3.3, 11.1.1]

1.2 Instruct patients to discontinue use of this product and contact the medical personnel immediately if cough, dyspnea, or pyrexia occurs. [See Section 11.1.1]

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)

2.1 Patients receiving interferon preparations [See Sections 10.1, 11.1.1]

2.2 Patients with cirrhosis or liver cancer [See Sections 1.1, 9.3.1-9.3.3, 11.1.1]

2.3 Patients with hepatic impairment in chronic hepatitis with a platelet count $\leq 100,000 /\text{mm}^3$ [See Sections 1.1, 8.4, 9.3.1-9.3.3, 11.1.1]

3. COMPOSITION AND PRODUCT DESCRIPTION**3.1 Composition**

| Brand name | OHSUGI Shosaikoto Extract Granules G | OHSUGI Shosaikoto Extract T Tablets |
|-------------------|---|---|
| Active ingredient | The daily dose of this product, 7.5 g, contains 4.0 g of the dried extract (Shosaikoto extract) from the following mixed crude drugs. | The daily dose of this product, 18 tablets, contains 4.0 g of the dried extract (Shosaikoto extract) from the following mixed crude drugs. |
| | JP Bupleurum Root | 7 g |
| | JP Pinellia Tuber | 5 g |
| | JP Ginger | 1 g |
| | JP Scutellaria Root | 3 g |
| | JP Jujube | 3 g |
| | JP Ginseng | 3 g |
| | JP Glycyrrhiza | 2 g |
| | JP : Japanese Pharmacopoeia | |
| Excipients | Lactose Hydrate, Corn Starch and Magnesium Stearate | Microcrystalline Cellulose, Magnesium Alumino-metasilicate, Carmellose Calcium, Magnesium Stearate, Hypromellose, Titanium Oxide, FD&C Yellow No.6 [Sunset Yellow FCF], FD&C Blue No.1 [Brilliant Blue FCF] and FD&C Red No.3 [Erythrosine] |

3.2 Product Description

| Brand name | OHSUGI Shosaikoto Extract Granules G | OHSUGI Shosaikoto Extract T Tablets |
|-------------|---|---|
| Dosage form | Granules | Film-coated tablets |
| Tone | Light grayish and dark brown-colored granules | Light brown-colored film-coated tablets |
| Smells | Uniquely | - |
| Tastes | Sweet initially and then hot slightly | - |
| Form | - | Front |
| | | Back |
| | | Side |
| Diameter | - | About 9.0 mm |
| Thickness | - | About 5.4 mm |
| Weight | - | About 330 mg |
| ID Code | SG-09 | SG-09 T |

4. INDICATIONS

1. The following symptoms in patients who have moderate physical strength, distress in the upper abdomen, coated tongue, oral discomfort, anorexia, and sometimes slight pyrexia and nausea: Acute febrile diseases of various kinds, pneumonitis, bronchiolitis, bronchial asthma, common cold, lymphadenitis, chronic gastrointestinal disorders, and complicated postpartum recovery
2. Improvement of hepatic impairment in chronic hepatitis

6. DOSAGE AND ADMINISTRATION

< OHSUGI Shosaikoto Extract Granules G >

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.

< OHSUGI Shosaikoto Extract T Tablets >

The usual adult dose is 18 tablets/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.

8. IMPORTANT PRECAUTIONS

< Common indications >

8.1 When this product is used, the patient's "SHO" (constitution/symptoms) should be taken into consideration. The patient's progress should be carefully monitored, and if no improvement in symptoms or findings is observed, continuous administration should be avoided.

8.2 Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc. [See Sections 10.2, 11.1.2, 11.1.3]

8.3 When this product is used in combination with other Kampo products, etc., attention should be paid to the duplication of the contained crude drugs.

< Improvement of hepatic impairment in chronic hepatitis >

8.4 During treatment with this product, attention should be paid to changes in the platelet count, and if a decreased platelet count is observed, administration should be discontinued. [See Sections 1.1, 2.3, 9.3.1-9.3.3, 11.1.1]

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 products should be used after confirmation that it is suitable for the identified "SHO" of the patient.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with extremely weakened constitution

Adverse reactions are likely to occur, and the symptoms may be aggravated.

9.3 Patients with Hepatic Impairment

9.3.1 Patients with cirrhosis or liver cancer

The product should not be administered. Interstitial pneumonia may occur, resulting in serious outcomes such as death. [See Sections 1.1, 2.2, 2.3, 8.4, 11.1.1]

9.3.2 Patients with hepatic impairment in chronic hepatitis with a platelet count of $\leq 100,000 /\text{mm}^3$

The product should not be administered. Cirrhosis is suspected. [See Sections 1.1, 2.2, 2.3, 8.4, 11.1.1]

9.3.3 Patients with hepatic impairment in chronic hepatitis with a platelet count greater than $100,000 /\text{mm}^3$ and less than or equal to $150,000 /\text{mm}^3$

This product should be administered with care. The patient may have cirrhosis. [See Sections 1.1, 2.2, 2.3, 8.4, 11.1.1]

9.5 Pregnant Women

This product should be used in pregnant women or women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

9.6 Breast-feeding Women

Considering the therapeutic benefits and the benefits of breastfeeding, continuation or discontinuation of breastfeeding should be considered.

9.7 Pediatric Use

No clinical studies have been conducted in children.

9.8 Geriatric Use

Since the physiological functions are generally decreased in elderly patients, careful supervision is recommended; measures such as reducing the dose may be considered.

10. INTERACTIONS

10.1 Contraindications for Co-administration (Do not co administer with the following.)

| Drugs | Signs, Symptoms, and Treatment | Mechanism and Risk Factors |
|--|-----------------------------------|----------------------------|
| Interferon preparations Interferon- α (Sumiferon, etc.) Interferon- β (Feron, etc.) [See Sections 2.1, 11.1.1] | Interstitial pneumonia may occur. | Mechanism unknown. |

10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)

| Drugs | Signs, Symptoms, and Treatment | Mechanism and Risk Factors |
|---|--|--|
| Glycyrrhiza-containing preparations Shakuyakukanzoto Hochuekkito Yokukansan, etc. Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/L-cysteine Monoammonium Glycyrrhizinate/Glycine/DL-Methionine combination tablets, etc. Loop diuretics Azosemide Torasemide Furosemide, etc. Thiazide diuretics Trichlormethiazide Hydrochlorothiazide Benzylhydrochlorothiazide, etc. [See Sections 8.2, 11.1.2, 11.1.3] | Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur. | Since glycyrrhizic acid and diuretics promote potassium excretion in renal tubules, it is considered that a decrease in the serum potassium level may be promoted. |

11. ADVERSE REACTIONS

The following adverse reactions may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

11.1 Clinically Significant Adverse Reactions

11.1.1 Interstitial Pneumonia (frequency unknown)

If cough, dyspnea, pyrexia, abnormal lung sound, etc. are observed, administration of this product should be discontinued, and examinations such as chest X-ray and chest CT scan should be performed immediately, and appropriate measures such as administration of corticosteroid should be taken. In addition, patients should be advised to discontinue administration of this product and contact the physician immediately if cough, dyspnea, or pyrexia, etc. occur. [See Sections 1.1, 1.2, 2.1-2.3, 8.4, 9.3.1-9.3.3, 10.1]

11.1.2 Pseudoaldosteronism (frequency unknown)

Pseudoaldosteronism such as hypokalaemia, blood pressure increased, retention of sodium/body fluid, edema, and body weight gain may occur. Patients should be carefully monitored (e.g., measurement of serum potassium levels), and if any abnormalities are observed, administration should be discontinued, and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

11.1.3 Myopathy, rhabdomyolysis (frequency unknown)

Since myopathy and rhabdomyolysis may occur as a result of hypokalaemia, patients should be carefully monitored, if feelings of weakness, muscle weakness, myalgia, limb muscle cramp/paralysis, increased CK, or rise of myoglobin in blood or urine are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

11.1.4 Hepatic impairment, jaundice (frequency unknown)

Hepatic impairment and/or jaundice with marked elevations of AST, ALT, Al-P, γ -GTP, etc. may occur.

11.2 Other Adverse Reactions

| | Frequency unknown |
|------------------|---|
| Hypersensitivity | Rash, pruritus, urticaria, etc. |
| Gastrointestinal | Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, constipation, etc. |
| Urinary | Pollakiuria, painful micturition, hematuria, feeling of residual urine, cystitis, etc. |

18. PHARMACOLOGY

18.1 Mechanism of action

The mechanism of action is not clear.

18.2 Inhibition of experimental hepatic damage^{1),2)}

Male Wistar rats were treated with carbon tetrachloride for 6 weeks to study the effects of the drug on lipid peroxidation and enzyme activity in the cell membrane pathology and microsomal fraction of the liver.

- ① In the microsomal fraction, the decrease in GSH-Px activity, one of the representative scavenging systems for lipid peroxide, was suppressed by the administration of the drug. The decrease in Na^+/K^+ -ATPase was similarly suppressed.
- ② The decrease in ICDH activity in the mitochondrial fraction was suppressed.
- ③ Cell membrane and mitochondrial damage was mild, and the degree of morphological damage was mild.

20. PRECAUTIONS FOR HANDLING

20.1 To maintain the quality of the product, avoid moisture as much as possible and store in a cool place, away from direct sunlight.

20.2 Avoid moisture, especially after opening, and handle with care.

20.3 Since this product is made from crude drugs, the color of the product may vary.

22. PACKAGING

< OHSUGI Shosaikoto Extract Granules G >

500 g [Bottle]

735 g (2.5 g × 294 packets) [Sachet]

210 g (2.5 g × 84 packets) [Sachet]

< OHSUGI Shosaikoto Extract T Tablets >

1,764 tablets (6 tablets × 294 packets) [Sachet]

504 tablets (6 tablets × 84 packets) [Sachet]

23. REFERENCES

- 1) Hiroyuki, I. The clinical report. 1990; 24(10): 5321-5324.
- 2) Hiroyuki, I. Medical Kanpo. 1991; 5: 11.

24. REFERENCE REQUEST AND CONTACT INFORMATION

Dep. of PMS Information,

Ohsugi Pharmaceutical Co., Ltd.

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06-6629-9058

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Marketing Authorization Holder

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