ID Code	SG-09

April 2014
(3rd version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

OHSUGI Shosaikoto Extract Granules G

(Shosaikoto)

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) 3876
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986
Date of latest reevaluation	March 1995 April 2014

WARNINGS

1. Treatment with this product may cause interstitial pneumonia, which may result in serious outcomes such as death unless appropriate measures are taken in the early phase. The patient should be carefully monitored and if fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), X-ray abnormalities, etc. are observed, administration of this product should be discontinued immediately.

2. The patient should be advised to discontinue this product and to contact the physician in the event of fever, cough, dyspnea, etc.
(Refer to the section "Clinically significant adverse reactions".)

CONTRAINDICATIONS (Shosaikoto is contraindicated in the following patients.)

1.Patients receiving treatment with interferon preparations
(Refer to the section "Drug Interactions")
2.Patients with liver cirrhosis or hepatoma [Interstitial pneumonia may occur and cause serious outcomes such as death.]
3.Patients with liver dysfunction in chronic hepatitis with a platelet count of 100,000/mm3 or below [Liver cirrhosis is suspected]

DESCRIPTION

(1) 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.
JP Bupleurum Root ---------- 7g
JP Jujube ---------- 3 g
JP Pinellia Tuber ---------- 5 g
JP Ginseng ---------- 3 g
JP Ginger ---------- 1 g
JP Glycyrrhiza ---------- 2 g
JP Scutellaria Root ---------- 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 uniquely, and tastes sweet initially and then hot slightly.
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INDICATIONS

1. Shosaikoto is indicated for the relief of the following symptoms of those patients with moderately strong constitution, right upper abdominal tenderness accompanied by fullness and discomfort, coated tongue, oral cavity discomfort, anorexia, and/or those with slight fever and nausea:
Various acute febrile diseases, pneumonia, bronchitis, common cold, lymphadenitis, chronic gastrointestinal disorder, and insufficient postpartum recovery
2. Shosaikoto is indicated for the improvement of liver dysfunction due to chronic hepatitis.

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 (Shosaikoto should be administered with care to the following patients.)

1) Patients with severe apophylaxis [Adverse reactions are likely to occur, and the symptoms may be aggravated.]
2) Patients with liver dysfunction in chronic hepatitis with a platelet count of 150,000/mm3 or below [The disease may have progressed to cirrhosis]

(2) Important Precautions

1) During treatment with this product for liver dysfunction in chronic hepatitis, attention should be paid to possible change in the platelet count, and if a decreased platelet count is observed, administration should be discontinued.
2) 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.
3) 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.
4) 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.

(3) Drug Interactions

1) Contraindication for coadministration (Shosaikoto should not be coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Interferon preparations Interferon-α Interferon-β	Interstitial pneumonia may occur. (Refer to the section "Clinically significant adverse reactions".)	The mechanism is not known.

2) Precautions for coadministration (this product 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 (3) Loop diuretics Furosemide Ethacrynic acid (4) Thiazide diuretics Trichloromethiazide	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 **Interstitial Pneumonia**: If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of this product should be discontinued, and examination such as chest X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones should be taken. Besides, the patient should be advised to discontinue this product immediately and to make contact with the physician in the event of fever, cough, dyspnea, etc.

② **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.

③ **Myopathy**: As a result of hypokalemia, myopathy and rhabdomyolysis may occur. If weakness, muscle weakness, myalgia, convulsions/paralysis of limbs, increased CK(CPK), increased blood/urinary myoglobin are observed, administration should be discontinued and appropriate measures such as administration of potassium preparation taken.

④ **Hepatic dysfunction and jaundice**: Hepatic dysfunction, with remarkable elevation of AST(GOT), ALT(GPT), Al-P and γ - GTP level, and/ or jaundice 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
Hypersensitivity Note 1)	Rash, Pruritus, Urticaria etc.
Gatrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, Constipation, etc.
Urinary Note 2)	Polakiuria, Micturition pain, Hematuria, Feeling of residual urine, Cystitis, etc.

Note 1) If such symptoms are observed, administration should be discontinued.

Note 2) Since these symptoms may occur. The patient should be carefully monitored, and if abnormalities observed, administration of this product should be discontinued and appropriate measures taken.

(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

The safety of this product in pregnant woman has not been established. Therefore, the product should be used in pregnant, women who may possibly be pregnant only if the expected therapeutic benefit outweigh the possible risks associated with treatment.

(7) Pediatric Use

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

PHRMACOLOGY

Experimental prevention of hepatopathy 1) 2)

The effect of this drug on the pathology of liver cell wall and peroxidation of fat and enzyme activity in the microzome fraction of male Wister rats treated with tetrachloro carbon for 6 weeks was investigated.

① The decrease of the GSH-Px activity, which is one of the typical elimination system of lipoperoxide in microzome fraction, was prevented..
The decrease of Na+/Ka+-ATPase was prevented as well.

② The decrease of ICDH activity in mitochondria fraction was prevented.

③ Injuries of cell wall and mitochondria and morphological changes were mild.

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

500 g
735 g (2.5 g x 294 packets)
210 g (2.5 g x 84 packets)

REFERENCES

1) Hiroyuki. Ito: Changes of cell wall associated with liver injuries by tetrachlorocarbon, and the effect of Shosaiko-to on the changes. Clinical Report 24(10)5321-5324, 1990

2) Hiroyuki. Ito: Improvement activity of Shosaiko-to on liver injuries. Medical Kanpo No. 5 (June 1991)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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