### - 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.

### 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]

### 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, 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]

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.

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**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.

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>JP Bupleurum Root</td>
<td>7 g</td>
</tr>
<tr>
<td>JP Jujube</td>
<td>3 g</td>
</tr>
<tr>
<td>JP Pinellia Tuber</td>
<td>5 g</td>
</tr>
<tr>
<td>JP Ginseng</td>
<td>3 g</td>
</tr>
<tr>
<td>JP Ginger</td>
<td>1 g</td>
</tr>
<tr>
<td>JP Glycyrrhiza</td>
<td>2 g</td>
</tr>
<tr>
<td>JP Scutellaria Root</td>
<td>3 g</td>
</tr>
</tbody>
</table>

(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.

ID Code: SG-09
(3) Drug Interactions

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

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Signs, Symptoms, and Treatment</th>
<th>Mechanism and Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interferon preparations</td>
<td>Interstitial pneumonia may occur. (Refer to the section “Clinically significant adverse reactions.”)</td>
<td>The mechanism is not known.</td>
</tr>
<tr>
<td>Interferon-α</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interferon-β</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Signs, Symptoms, and Treatment</th>
<th>Mechanism and Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparations containing Glycyrrhiza</td>
<td>Pseudoadalsteronism is likely to occur. Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section “Clinically significant adverse reactions.”)</td>
<td>Since glycyrrhizic 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.</td>
</tr>
<tr>
<td>Preparations containing glycyrrhizic acid or glycyrrhizates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loop diuretics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Furosemide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethacrynic acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thiazide diuretics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trichloromethiazide</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(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

- **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.

- **Pseudoadalsteronism**: Pseudoadalsteronism 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.

- **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.

- **Hepatic dysfunction and jaundice**: Hepatic dysfunction, with remarkable elevation of AST (GOT), ALT (GPT), Al-P and \( \gamma \)-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

<table>
<thead>
<tr>
<th>Incidence Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypersensitivity</td>
</tr>
<tr>
<td>Note 1)</td>
</tr>
<tr>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>Urinary</td>
</tr>
</tbody>
</table>

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 women 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]

PHARMACOLOGY

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 microzone 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 microzone fraction, was prevented.

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. Medical Kanpo No. 5 (June 1991)
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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