Revised: August 2017 (6th version)

| Standard Commodity Classification No. of Japan |
|---|
| 875200 |

- Kampo-preparation -

# TEIKOKU Goshakusan Extract Granules

< Goshakusan >

| Storage |
|---|
| Store at room temperature in a tight container. [See the "Precaution for handling" section.] |

| Expiration date |
|---|
| Goshakusan should be used before the expiration date indicated on the label and the package. |

| | |
|---|---|
| Approval No. | (61AM) 3748 |
| Date of listing in the NHI reimbursement price | October 1987 |
| Date of initial marketing in Japan | October 1987 |

## DESCRIPTION

| | | |
|---|---|---|
| Composition | 7.5 g of TEIKOKU Goshakusan Extract Granules contains 3.12 g of a dried water extract of the following mixed crude drugs.<br>JP Poria Sclerotium ---------- 2.0 g<br>JP Atractylodes Rhizome---------- 3.0 g<br>JP Citrus Unshiu Peel ---------- 2.0 g<br>JP Pinellia Tuber ---------- 2.0 g<br>JP Japanese Angelica Root ------ 2.0 g<br>JP Peony Root ---------- 1.0 g<br>JP Cnidium Rhizome ---------- 1.0 g<br>JP Magnolia Bark ---------- 1.0 g<br>JP Angelica Dahurica Root ------ 1.0 g<br>JP Immature Orange ---------- 1.0 g<br>JP Platycodon Root ---------- 1.0 g<br>JP Ginger ---------- 0.3 g<br>JP Processed Ginger ---------- 1.0 g<br>JP Cinnamon Bark ---------- 1.0 g<br>JP Ephedra Herb ---------- 1.0 g<br>JP Jujube ---------- 1.0 g<br>JP Glycyrrhiza ---------- 1.0 g<br>(JP: The Japanese Pharmacopoeia) | |
| | Inactive ingredients | JP Lactose Hydrate<br>JP Microcrystalline Cellulose<br>JP Magnesium Stearate |
| Description | Dosage form | Granules |
| | Color | Light brown |
| | Smell | Characteristic smell |
| | Taste | Sweet and bitter |
| | ID code | TEIKOKU 63 |

## INDICATIONS

The following symptoms that take a chronic course without severe symptoms:

Gastroenteritis, low back pain, neuralgia, arthralgia, menses painful, headache, oversensitivity to cold, climacteric disturbance, and common cold

## DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Goshakusan Extract Granules three times daily before meals.

The dosage may be adjusted according to the patient's age, body weight, and symptoms.

## PRECAUTIONS

**1. Careful Administration (Goshakusan should be administered with care in the following patients.)**

(1) Patients in a period of weakness after disease or with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

(2) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]

(3) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]

(4) Patients showing a remarkable tendency of sweating [Excess sweating and/or generalized weakness may occur.]

(5) Patients with cardiovascular disorders including angina pectoris and myocardial infarction, etc. or those with a history of such disorders.

(6) Patients with severe hypertension

(7) Patients with severe renal dysfunction

(8) Patients with dysuria

(9) Patients with hyperthyroidism

[(5)-(9): These disease and 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) 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-preparations (Japanese traditional herbal medicines), etc., attention should be paid to the duplication of the contained crude drugs.

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-preparations (Japanese traditional herbal medicines) should be used after confirmation that it is suitable for the identified "SHO" of the patient.

**3. Drug Interactions**

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

| Drugs | Signs, Symptoms, and Treatment | Mechanism and Risk Factors |
|---|---|---|
| Preparations containing Ephedra Herb<br><br>Preparations containing ephedrine related compounds<br><br>Monoamine oxidase (MAO) inhibitors<br><br>Thyroid preparations<br>Thyroxine<br>Liothyronine<br><br>Catecholamine preparations<br>Adrenaline<br>Isoprenaline<br><br>Xanthine prepartions<br>Theophylline<br>Diprophylline | Insomnia, excessive sweating, tachycardia, palpitation, general weakness, mental excitation, etc. are likely to occur.<br>In such cases, this product should be administered with care by measures such as reducing the dosage. | An enhancement of the sympathetic nerve-stimulating action has been suggested. |
| Preparations containing Glycyrrhiza<br><br>Preparations containing glycyrrhizinic acid or glycyrrhizinates | 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) 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) | Rash, Redness, Pruritus, etc. |
| **Autonomic** | Insomnia, Excess sweating, Tachycardia, Palpitation, Generalized weakness, Mental excitation, etc. |
| **Gastrointestinal** | Anorexia, Epigastric distress, Nausea, Vomiting, Diarrhea, etc. |
| **Urinary** | Urination disorder, etc. |

Note) 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.

**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, 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.]

## PRECAUTIONS FOR HANDLING

1.This product should not be stored in direct rays and should be stored in a cool place with, if possible, little humidity.

2.Since it is hygroscopic property, this product should not be stored in humid places after opening.

## PACKAGING

Bottles of 500 g

Boxes of 2.5 g×42 packets

Boxes of 2.5 g×252 packets

**REQUEST FOR LITERATURE SHOULD BE MADE TO:**

Product Information Unit,
Pharmaceutical Sales & Marketing Dept.
Teikoku Seiyaku Co., Ltd.
6-6 Nihonbashi-kobunacho, Chuo-Ku, Tokyo
103-0024, Japan
Tel 0120-189-567

**Manufactured by:**
Teikoku Kampo Seiyaku Co., Ltd.
80-11 Kitahara, Donari, Donari-cho, Awa, Tokushima
771-1506, Japan

**Distributed by:**
Teikoku Seiyaku Co., Ltd.
567, Sanbonmatsu, Higashikagawa, Kagawa
769-2695, Japan