

Revised: February 2018 (7th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Saikoseikanto Extract Granules

< Saikoseikanto >

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

Approval No.	(61AM) 3695
Date of listing in the NHI reimbursement price	July 1988
Date of initial marketing in Japan	July 1988

Expiration date
Saikoseikanto should be used before the expiration date indicated on the label and the package.

DESCRIPTION

Composition	9.0 g of TEIKOKU Saikoseikanto Extract Granules contains 4.48 g of a dried water extract of the following mixed crude drugs.	
		JP Bupleurum Root ----- 2.0 g JP Japanese Angelica Root ----- 1.5 g JP Peony Root ----- 1.5 g JP Cnidium Rhizome ----- 1.5 g JP Rehmannia Root ----- 1.5 g JP Coptis Rhizome ----- 1.5 g JP Scutellaria Root ----- 1.5 g JP Phellodendron Bark ----- 1.5 g JP Gardenia Fruit ----- 1.5 g JP Forsythia Fruit ----- 1.5 g JP Platycodon Root ----- 1.5 g JP Burdock Fruit ----- 1.5 g JP Trichosanthes Root ----- 1.5 g JP Mentha Herb ----- 1.5 g JP Glycyrrhiza ----- 1.5 g (JP: The Japanese Pharmacopoeia)
	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
Description	Dosage form	Granules
	Color	Light yellowish brown
	Smell	Slightly characteristic smell
	Taste	Extremely bitter
	ID code	TEIKOKU 80

PRECAUTIONS

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

- (1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]
- (2) Patients with anorexia, nausea or vomiting [These 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) Long-term administration of a gardenia fruit-containing preparation (usually 5 years or longer) may cause mesenteric phlebosclerosis accompanied by discoloration, edema, erosion, ulceration, and stenosis of the colon. Periodical examinations such as CT scanning and colonoscopy would be desirable in cases of its long-term administration.
- (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.

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.

INDICATIONS

The following symptoms in children who tend to be irritable:
Neurosis, chronic tonsillitis, and eczema

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 3.0 g of TEIKOKU Saikoseikanto Extract Granules three times daily before meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

3. Drug Interactions

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

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

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.

3) Mesenteric phlebosclerosis: Mesenteric phlebosclerosis may occur with long-term administration. If symptoms such as abdominal pain, diarrhea, constipation, and abdominal distension repeatedly occur, or if the patient tests positive for fecal occult blood, administration should be discontinued. At the same time, tests such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases.

(2) Other adverse reactions

	Incidence unknown
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Diarrhea, etc.

5. 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.

6. 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 3.0 g× 42 packets
- Boxes of 3.0 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