

Revised: August 2017 (7th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU San'oshashinto Extract Granules

< San'oshashinto >

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

Approval No.	(61AM) 3676
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

Expiration date
San'oshashinto should be used before the expiration date indicated on the label and the package.

DESCRIPTION

Composition	7.5 g of TEIKOKU San'oshashinto Extract Granules contains 1.21 g of a dried water extract of the following mixed crude drugs.	
	JP Rhubarb -----	3.0 g
	JP Scutellaria Root -----	3.0 g
	JP Coptis Rhizome -----	3.0 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 113

INDICATIONS

The following symptoms of those patients with a comparatively strong constitution who have a slight feeling of hot flush and have facial hot flushes, mental instability, and are likely to have constipation:

Symptoms associated with hypertension (flushing, shoulder stiffness, tinnitus, dull headache, insomnia, and anxiety), nose bleeding, hemorrhoidal bleeding, constipation, climacteric disturbance, and automatic imbalance syndrome peculiar to women resembling climacteric disturbance

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 2.5 g of TEIKOKU San'oshashinto 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 (San'oshashinto should be administered with care in the following patients.)

- (1) Patients with diarrhea, soft feces [These symptoms may be aggravated.]
- (2) Patients with an extremely weak gastrointestinal tract [Anorexia, abdominal pain, diarrhea, etc. may occur.]
- (3) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the 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) 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. Special caution should be exercised when this product is coadministered with preparations containing Rhubarb.
- (3) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

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. 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, etc. are observed, administration of this product should be discontinued, and examinations such as X-ray or chest CT should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken.

2) Hepatic dysfunction and jaundice: Hepatic dysfunction and/or jaundice with remarkable elevation of AST (GOT), ALT (GPT), ALP and γ -GTP or other symptoms 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
Gastrointestinal	Anorexia, Abdominal pain, Diarrhea, etc.

4. Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

5. Use during Pregnancy, Delivery or Lactation

(1) Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in this product may cause premature birth or abortion.]

(2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in breast milk and induce diarrhea in nursing infants.]

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 2.5 g× 42 packets
- Boxes of 2.5 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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