Revised: August 2017 (7th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Goreisan Extract Granules

< Goreisan >

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

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

Approval No.	(61AM) 3866
Date of listing in the NHI reimbursement price	July 1988
Date of initial marketing in Japan	July 1988

DESCRIPTION

Composition	7.5 g of TEIKOKU Goreisan Extract Granules contains 1.69 g of a dried water extract of the following mixed crude drugs. JP Alisma Tuber ---------- 5.0 g JP Polyporus Sclerotium --------- 3.0 g JP Poria Sclerotium ---------- 3.0 g JP Atractylodes Rhizome -------- 3.0 g JP Cinnamon Bark ---------- 2.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
Description	Dosage form	Granules
	Color	Light brown
	Smell	Characteristic smell
	Taste	Sweet and bitter
	ID code	TEIKOKU 17

INDICATIONS

The following symptoms of those patients with thirst and decreased urine volume who have nausea or vomiting or stomachache or headache or swelling, etc.:
Watery diarrhea, acute gastroenteritis (do not use for tenesmus alvi), heat exhaustion, headache, and edema

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Goreisan Extract Granules three times daily before meals.
The dosage may be adjusted according to the patient’s age, body weight, and symptoms.

PRECAUTIONS

1. 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.

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.

2. 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.

	Incidence unknown
Hypersensitivity Note)	Rash, Redness, Pruritus, etc.
Hepatic	Abnormality of hepatic function [Increased AST (GOT) , ALT (GPT) and γ-GTP , etc. levels]

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

3. Use in the Elderly

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

4. 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.

5. 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.
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