Revised: October 2014 (6th version)

Standard Commodity Classification No. of Japan
875200

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- Kampo-preparation-

TSUMURA Goreisan Extract Granules for Ethical Use

Storage
Store in light-resistant, air-tight containers.

Expiration date
Use before the expiration date indicated on the container and the outer package.

Approval No.	(61AM)3287
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

DESCRIPTION

Composition	7.5 g of TSUMURA Goreisan extract granules (hereafter TJ-17) contains 2.0 g of a dried extract of the following mixed crude drugs. JP Alisma Rhizome ..... 4.0 g JP Atractylodes Lancea Rhizome ..... 3.0 g JP Polyporus Sclerotium ..... 3.0 g JP Poria Sclerotium ..... 3.0 g JP Cinnamon Bark ..... 1.5 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Light grayish-brown
	Smell	Characteristic smell
	Taste	Slightly pungent
	ID code	TSUMURA/17

INDICATIONS

TJ-17 is indicated for the relief of the following symptoms of those patients with oral dryness and decreased urine volume: Edema, nephrosis, alcoholic hangover, acute gastrointestinal catarrh, diarrhea, nausea, vomiting, dizziness, water retention in the stomach, headache, uremia, heat-stroke, and diabetes mellitus

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 g/day orally in 2 or 3 divided doses before or between meals. The dosage may be adjusted according to the patient's age and body weight, and symptoms.

PRECAUTIONS

1. Important Precautions

(1) When TJ-17 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 TJ-17 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

TJ-17 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 1)	Rash, Redness, Pruritus, etc.
Hepatic	Abnormality of hepatic function [Increased AST (GOT) , ALT (GPT) and γ-GTP etc]

Note 1) 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 TJ-17 in pregnant women has not been established. Therefore, TJ-17 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 TJ-17 in children has not been established. [Insufficient clinical data.]

PHARMACOLOGY

1. Antidiarrheic effect

Oral administration of Goreisan to mice inhibited the diarrhea induced by magnesium sulfate[1].

2. Hydragogue effect

Oral administration of Goreisan to mice increased the urine volume in water intoxication mice but not in water deprivation mouse[2].

3. Actions on dry mouth

Oral administration of Goreisan to diabetic xerostomia mouse models inhibited the decrease in the salivation rate[3].

4. Action mechanism

Goreisan shows pharmacological effects via the following actions.

(1) Diuretic action

Goreisan inhibited the Na^+ channel in cells derived from the cortical collecting tubule (MDCK cells) in the distal tubule derived from the dog kidneys (*in vitro*) [4].

(2) Increasing effect on urine volume

Oral administration of Goreisan to rats downregulted aquaporin (AQP)3 mRNA in renal cortex as well as AQP2 mRNA and AQP3 mRNA in renal medulla, subsequently increased the urine volume[5].

PACKAGING

Bottles of 500 g and boxes of 5 kg (500 g × 10 bottles)
2.5 g × 42 packets
2.5 g × 189 packets

REFERENCES

1) Okamura, S.et al. Jpn. J. Oriental Medicine. 2009, 60(5), p.493.
2) Ohnishi, K. et al. J. Med. Pharm. Soc. WAKAN- YAKU. 2000, 17(3), p.131.
3) Itai, J. et al. The Journal of Japan Dental Society of Oriental Medicine. 2008, 27(1-2), p.9. (in Japanese)
4) Kuwahara, M. et al. Kidney and Dialysis. 1996, 14(2), p.251.
5) Kurita, T. et al. J. Med. Sci. 2011, 11(1), p.30.

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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