Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

■40■

- Kampo-preparation-

TSUMURA Choreito 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)3282
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 Choreito extract granules (hereafter TJ-40) contains 2.5 g of a dried extract of the following mixed crude drugs. JP Alminum Silicate Hydrate with Silicon Dioxide ..... 3.0 g JP Alisma Rhizome ..... 3.0 g JP Polyporus Sclerotium ..... 3.0 g JP Poria Sclerotium ..... 3.0 g Donkey Glue..... 3.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Light grayish-white
	Small	Characteristic smell
	Taste	Slightly Bitter
	ID code	TSUMURA/40

INDICATIONS

TJ-40 is indicated for the relief of the following symptoms of those patients who complain of decreased urine volume, dysuria, and oral dryness:

Urethritis, nephritis, renal calculus, blennorrhagic inflammation, micturition pain, hematuria, edema of the lower part of the body from the waist down, feeling of residual urine, and diarrhea

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-40 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-40 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-40 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.
Gastrointestinal	Epigastric distress, 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-40 in pregnant women has not been established. Therefore, TJ-40 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-40 in children has not been established. [Insufficient clinical data]

PHARMACOLOGY

1. Inhibition of stone formation

(1) Administration of food containing Choreito to adult SPF cats reduced the increased urinary pH and phosphorus concentration, and increased the solubility of ammonium magnesium phosphate hexahydrate (struvite) (*in vitro*) [1].

(2) Oral administration of Choreito to model rats with calcium oxalate stones inhibited both an increase in stones and stone-induced hydronephrosis or hydroureter and reduced the calcium content in renal tissue[2].

(3) Administration of food containing Choreito mixed magnesium to cats reduced the urinary phosphorus concentration, the amount of struvite stones, and the degree of hematuria[3].

2. Anti-nephritic action

(1) Oral administration of Choreito to rats with immune complex nephritis (IC nephritis) reduced urinary protein excretion, serum total cholesterol, and blood urea nitrogen[4].

(2) Oral administration of Choreito to rats reduced urinary protein excretion and inhibited the increase in urinary NAG excretion and the epithelial cell damage of the proximal tubule induced by subcutaneous injection of gentamicin[5].

PACKAGING

Bottles of 500 g
2.5 g × 42 packets
2.5 g × 189 packets

REFERENCES

1)Buffington, C. A. et al. Am. J. Vet. Res. 1994, 55(7), p.972.
2)Yoshioka, T. et al. Prog. Med. 1996, 16(2), p.195.
3)Buffington, C. A. et al. Am. J. Vet. Res. 1997, 58(2) p.146.
4)Kubo, M. et al. J. Med. Pharm. Soc. WAKAN-YAKU. 1989, 6(2), p.115.
5)Kyo, K. et al. KANPO IGAKU. 1993, 17(7), p.237.

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