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Standard Commodity Classification No. of Japan
875200



- Kampo-preparation-

## TSUMURA Hachimijiogan Extract Granules for Ethical Use

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

Approval No.	(61AM)3285
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

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

### DESCRIPTION

Composition	7.5 g of TSUMURA Hachimijiogan extract granules (hereafter TJ-7) contains 4.0 g of a dried extract of the following mixed crude drugs.	
		JP Rehmannia Root ..... 6.0 g JP Cornus Fruit ..... 3.0 g JP Dioscorea Rhizome ..... 3.0 g JP Alisma Rhizome ..... 3.0 g JP Poria Sclerotium ..... 3.0 g JP Moutan Bark ..... 2.5 g JP Cinnamon Bark ..... 1.0 g JP Powdered Processed Aconite Root ..... 0.5 g (JP: The Japanese Pharmacopoeia)
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate Sucrose Esters of Fatty Acids
Description	Dosage form	Granules
	Color	Grayish-brown
	Smell	Characteristic smell
	Taste	Bitter
	ID code	TSUMURA/7

### INDICATIONS

TJ-7 is indicated for the relief of the following symptoms of those patients with severe fatigue or malaise, decreased urinary output or increased urinary frequency, dry mouth, and alternate cold and hot feeling in the extremities:

Nephritis, diabetes mellitus, impotence, sciatica, low back pain, beriberi, cystorrhea, prostatic hypertrophy and hypertension

### 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. Careful administration (TJ-7 should be administered with care in the following patients.)

- (1) Patients with strong constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]
- (2) Patients with sensitivity to heat, a tendency towards hot flush and red face. [Palpitation, hot flush, numbness of the tongue, nausea, etc. may occur.]
- (3) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, feeling of enlarged abdomen, diarrhea, constipation, etc. may occur.]
- (4) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]

#### 2. Important Precautions

- (1) When TJ-7 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-7 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 Aconite Root.

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

TJ-7 has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

	<b>Incidence unknown</b>
<b>Hypersensitivity</b> Note 1)	Rash, Redness, Pruritus, etc.
<b>Hepatic</b>	Abnormality of hepatic function [increased AST (GOT), ALT (GPT), and total bilirubin levels, etc.]
<b>Gastrointestinal</b>	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, Constipation, etc.
<b>Others</b>	Palpitation, Hot flush, Numbness of the tongue, etc.

Note 1) If such symptoms are observed, administration should be discontinued.

#### 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

Use of TJ-7 in pregnant women, women who may possibly be pregnant is not recommended. [Moutan Bark contained in TJ-7 may cause premature birth or abortion. Besides, adverse reactions due to Powdered Processed Aconite Root contained in TJ-7 are likely to occur.]

#### 6. Pediatric Use

TJ-7 should be administered with care in children. [TJ-7 contains Powdered Processed Aconite Root.]

### PHARMACOLOGY

#### 1. Anti-diabetic action

Hachimijiogan, which was administered orally to rats, inhibited streptozotocin-induced increases in the blood glucose levels, water intake, the urine volume, and food intake. Immunohistochemical observation revealed that Hachimijiogan inhibited decrease in the number of pancreatic B cells due to streptozotocin<sup>1)</sup>.

#### 2. Effects on bone metabolism

- (1) Hachimijiogan, which was orally administered to ovariectomized rats, inhibited decrease in the levels of calcium in the tibia<sup>2)</sup>.
- (2) Hachimijiogan, which was orally administered to rats, inhibited decrease in the femoral mass under the low-estrogen conditions caused by a GnRH agonist, and increased the bone formation rate (BFR) of the tibia<sup>3)</sup>.

#### 3. Effects on spermatogenic function

- (1) Hachimijiogan, which was administered orally to immature or castrated mature rats, increased the prostatic thymidine kinase activity<sup>4)</sup>.
- (2) Oral administration of Hachimijiogan decreased the damage of spermatogenic function caused by adriamycin in mice<sup>5)</sup>.

#### 4. Anti-hypertensive action

Hachimijiogan, which was administered to orally introductory-MHR (rats under the induction phase of hypertension induced by metyrapone and heat stress-loading), inhibited increase in the blood pressure<sup>6)</sup>.

#### 5. Effect on the kidney

- (1) Hachimijiogan, which was mixed with salt-loaded diet and administered to Dahl salt-sensitive rats, inhibited

decrease in the glomerular filtration and improved injuries of the glomerular and the renal vascular tissues<sup>7)</sup>.

- (2) Administration of Hachimijiogan with feed suppressed the elevated level of calcium excretion into urine and suppressed the increase of thyroid hormone-concentration in blood in elderly mice<sup>8)</sup>.

### 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) Luo, W. Q. et al. *Biomed. Res.* 1998, 19(2), p.127.
- 2) Sassa, S. et al. *Recent progress of KAMPO MEDICINE in obstetrics and gynecology* No.10. Shindan to Chiryosha, 1993, p.46.
- 3) Kaneko, H. et al. *J. Jpn. Menopause Soc.* 1995, 3(2), p.225.
- 4) Sakamoto, S. et al. *Recent progress of KAMPO MEDICINE in obstetrics and gynecology* No.4. Shindan to Chiryosha, 1987, p.98.
- 5) Sudou, K. et al. *J. Med. Soc. Of Toho University.* 1991, 38(4), p.476.
- 6) Tei, M. et al. *J. Med. Pharm. Soc. WAKAN-YAKU.* 1989, 6(3), p.416.
- 7) Uehara, Y. et al. *Prog. Med.* 1994, 14(6), p.1761.
- 8) Ikeda, R. Et al. *J. Ethnopharmacol.* 2009, 124, p.176.

### REQUEST FOR LITERATURE SHOULD BE MADE TO:

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