Revised: August 2007 (7th version)

Standard Commodity Classification No. of Japan
875200

■127■

- Kampo-preparation-

TSUMURA Maobushisaishinto 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.	(62AM)693
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

Composition	7.5 g of TSUMURA Maobushisaishinto extract granules (hereafter TJ-127) contains 1.50 g of a dried extract of the following mixed crude drugs. JP Ephedra Herb ..... 4.0 g JP Asiasarum Root ..... 3.0 g JP Powdered Processed Aconite Root ..... 1.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Light Anhydrous Silicic Acid JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Dark gray
	Smell	Characteristic smell
	Taste	Slightly sweet and pungent
	ID code	TSUMURA/127

INDICATIONS

TJ-127 is indicated for the relief of the following symptoms of those patients with rigors, slight fever, general malaise, headache and dizziness with hypotension, and painfully cold limbs: Common cold and bronchitis

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-127 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 [Dry mouth, anorexia, epigastric distress, nausea, vomiting, etc. may occur.]

(4) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]

(5) Patients showing a remarkable tendency of sweating [Excess sweating and/or generalized weakness may occur.]

(6) Patients with cardiovascular disorders including angina pectoris and myocardial infarction, etc. or those with a history of such disorders.

(7) Patients with severe hypertension

(8) Patients with severe renal dysfunction

(9) Patients with dysuria

(10) Patients with hyperthyroidism

[(6)-(10): These disease and symptoms may be aggravated.]

2. Important Precautions

(1) When TJ-127 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-127 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. Drug Interactions

Precautions for coadministration (TJ-127 should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Ephedra Herb (2) Preparations containing ephedrine-related compounds (3) Monoamine oxidase (MAO) inhibitors (4) Thyroid preparations Thyroxine Liothyronine (5) Catecholamine preparations Adrenaline Isoprenaline (6) Xanthine preparations Theophylline Diprophylline	Insomnia, excessive sweating, tachycardia, palpitation, general weakness, mental excitation, etc. are likely to occur. In such cases, TJ-127 should be administered with care by measures such as reducing the dosage.	An enhancement of the sympathetic nerve-stimulating action has been suggested.

4. Adverse Reactions

TJ-127 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

Hepatic dysfunction and jaundice: Hepatic dysfunction and/or jaundice with elevation of AST (GOT), ALT (GPT), Al-P 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
Hypersensitivity Note 1)	Rash, Redness, etc.
Autonomic	Insomnia, Excess sweating, Tachycardia, Palpitation, Generalized weakness, Mental excitation, etc.
Gastrointestinal	Dry mouth, Anorexia, Epigastric distress, Nausea, Vomiting, etc.
Urinary	Urination disorder, etc.
Others	Hot flush, Numbness of the tongue, etc.

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

5. Use in the Elderly

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

6. Use during Pregnancy, Delivery or Lactation

Use of TJ-127 in pregnant women, women who may possibly be pregnant is not recommended. [Adverse reactions due to Powdered Processed Aconite Root contained in this product are likely to occur.]

7. Pediatric Use

TJ-127 should be administered with care in children. [TJ-127 contains Powdered Processed Aconite Root powder.]

PHARMACOLOGY

1. Anti-inflammatory effects

(1) Oral pretreatment with Maobushisaishinto in mice inhibited acetic acid-induced vascular permeability, arachidonic acid- or phorbol ester-induced ear edema, and the histamine- or bradykinin-induced increase of dermal vascular permeability[1].

(2) Oral pretreatment with Maobushisaishinto inhibited carrageenin-induced hind foot edema in rats. Furthermore, oral administration of Maobushisaishinto to rats in which a cotton pellet had been implanted inhibited the granulation tissue growth[1].

2. Anti-nociceptive effects

(1) Oral administration of Maobushisaishinto showed anti-nociceptive effects on acetic acid-induced writhing, tail-flick, tail-pressure and repeated cold stress (RCS) model mice[2].

(2) Oral administration of Maobushisaishinto exhibited anti-nociceptive effects in carrageenin-induced inflammatory pain model and adjuvant-induced arthritic pain model rats[2].

3. Action mechanism

Maobushisaishinto shows pharmacological effects via the following effects:

Anti-nociceptive effects

Oral administration of Maobushisaishinto showed anti-nociceptive effect in rat RCS–induced hyperalgesic rats. The antinociception was reduced by pretreatment via intrathecal injection of a serotonergic neurotoxin, 5,7-DHT, or serotonin receptor antagonists (methysergide, cyproheptadine, methiothepine). An intrathecal pretreatment of catecholaminergic neurotoxin, 6-OHDA, inhibited the maximum anti-nociceptive effects. However, the effects were less marked than those of 5,7-DHT, and were not influenced by pretreatment with an α-adrenergic antagonist (phentolamine) [3].

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) Ikeda, Y. et al. Am. J. Clin. Med. 1998, 26(2), p.171.
2) Ikeda, Y. et al. J. Traditional Med. 1996, 13(1), p.81.
3) Satoh, K. et al. PAIN AND KAMPO MEDICINE. 1998, 8, p.33.

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Consumer Information Services Center
Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan
TEL:0120-329970 FAX:03-5574-6610

Manufactured and Distributed by:

Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan