Revised: March 2013 (6th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Mokuboito Extract Granules for Ethical Use

<mokuboito>

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)1134
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 Mokuboito extract granules contains 1.5 g of a dried extract of the following mixed crude drugs. JP Gypsum ..... 10.0 g JP Sinomenium Stem ..... 4.0 g JP Cinnamon Bark ..... 3.0 g JP Ginseng ..... 3.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Light grayish-white
	Smell	Characteristic smell
	Taste	Bitter
	ID code	TSUMURA/36

INDICATIONS

TSUMURA Mokuboito Extract Granules (hereafter TJ-36) is indicated for the relief of diseases originating from the heart or kidneys, as well as edema and cardiac asthma, of those patients with a bad complexion, dyspnea with coughing, and tension and heaviness under the heart.

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-36 should be administered with care in the following patients.)

Patients with weak gastrointestinal tract [Anorexia, epigastric distress, soft feces, diarrhea, etc. may occur.]

2. Important Precautions

(1) When TJ-36 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-36 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.

3. Adverse Reactions

TJ-36 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, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Soft feces, Diarrhea, 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

The safety of TJ-36 in pregnant women has not been established. Therefore, TJ-36 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.

6. Pediatric Use

The safety of TJ-36 in children has not been established. [Insufficient clinical data]

PHARMACOLOGY

Actions on a Congestive heart failure model

The oral administration of TJ-36 in a mouse congestive heart failure induced by viral myocarditis improved the survival rate and histopathological score[1)].

PACKAGING

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

REFERENCES

1) Wang, W. Z. et al. Life Sci. 1998, **62**(13), p.1139.

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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