

Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

■46■

- Kampo-preparation -

TSUMURA Shichimotsukokato Extract Granules for Ethical Use

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

Approval No.	(61AM)3309
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 Shichimotsukokato extract granules (hereafter TJ-46) contains 4.0 g of a dried extract of the following mixed crude drugs.	
		JP Peony Root 4.0 g JP Japanese Angelica Root 4.0 g JP Astragalus Root 3.0 g JP Rehmannia Root 3.0 g JP Cnidium Rhizome 3.0 g JP Uncaria Hook 3.0 g JP Phellodendron Bark 2.0 g (JP: The Japanese Pharmacopoeia)
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Grayish-brown
	Smell	Characteristic smell
	Taste	Acrid
	ID code	TSUMURA/46

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

2. Important Precautions

- (1) When TJ-46 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-46 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.

INDICATIONS

TJ-46 is indicated for the relief of the following symptoms of those patients with a slightly delicate constitution:

Symptoms associated with hypertension (flushing, shoulder stiffness, tinnitus, and dull headache)

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-46 should be administered with care in the following patients.)

- (1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]

3. Adverse Reactions

TJ-46 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
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Diarrhea, etc.

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-46 in pregnant women has not been established. Therefore, TJ-46 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-46 in children has not been established.
[Insufficient clinical data]

PHARMACOLOGY

Inhibition of blood pressure-raising

Administration of Shichimotsukokato with a high-salt diet to salt-sensitive Dahl rats decreased the systolic blood pressure and glomerular sclerosing index¹⁾.

PACKAGING

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

REFERENCES

1)Hiwara, N. et al. Am. J. Chin. Med. 1994, 22(1), p.51.

■ REQUEST FOR LITERATURE SHOULD BE MADE TO:

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