

Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Mashiningan Extract Granules for Ethical Use

<mashiningan>

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

Approval No.	(61AM)1171
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 Mashiningan extract granules contains 2.25 g of a dried extract of the following mixed crude drugs.	
		JP Hemp Fruit 5.0 g JP Rhubarb 4.0 g JP Immature Orange 2.0 g JP Apricot Kernel 2.0 g JP Magnolia Bark 2.0 g JP Peony Root 2.0 g (JP: The Japanese Pharmacopoeia)
Description	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
	Dosage form	Granules
	Color	Yellow-brown
	Smell	Characteristic smell
	Taste	Bitter and astringent
	ID code	TSUMURA/126

INDICATIONS

TSUMURA Mashiningan Extract Granules (hereafter TJ-126) is indicated for the relief of the following symptoms:
Constipation

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-126 should be administered with care in the following patients.)

- (1) Patients with diarrhea, soft feces [These symptoms may be aggravated.]
- (2) Patients with an extremely weak gastrointestinal tract [Anorexia, abdominal pain, diarrhea, etc. may occur.]

2. Important Precautions

- (1) When TJ-126 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-126 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 TJ-126 is coadministered with preparations containing Rhubarb.
- (3) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

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-126 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, Abdominal pain, 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

- (1) Use of TJ-126 in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in this product may cause premature birth or abortion.]
- (2) TJ-126 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-126 may be excreted in breast milk and induce diarrhea in nursing infants.]

6. Pediatric Use

The safety of TJ-126 in children has not been established.
[Insufficient clinical data]

PACKAGING

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

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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

Manufactured and Distributed by:

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