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Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

# TSUMURA Daijokito Extract Granules for Ethical Use

&lt;daijokito&gt;

<b>Storage</b>
Store in light-resistant, air-tight containers.

<b>Expiration date</b>
Use before the expiration date indicated on the container and the outer package.

Approval No.	(61AM)1163
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 Daijokito extract granules contains 3.0 g of a dried extract of the following mixed crude drugs.	
	JP Magnolia Bark ..... 5.0 g JP Immature Orange ..... 3.0 g JP Rhubarb ..... 2.0 g Anhydrous Mirabilitum ..... 1.3 g (JP: The Japanese Pharmacopoeia)	
Description	Inactive ingredients	JP Light Anhydrous Silicic Acid JP Magnesium Stearate JP Lactose Hydrate
	Dosage form	Granules
Description	Color	Yellow-brown
	Smell	Characteristic smell
	Taste	Slightly bitter
	ID code	TSUMURA/133

## INDICATIONS

TSUMURA Daijokito Extract Granules (hereafter TJ-133) is indicated for the relief of the following symptoms of those patients who have constipation associated with hardness of and a blocked feeling in the abdomen or those patients who have constipation predisposed to obesity:

Chronic constipation, acute constipation, hypertension, neurosis, and food poisoning

## 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-133 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.]
- (3) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

### 2. Important Precautions

- (1) When TJ-133 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-133 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-133 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-133 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>Gastrointestinal</b>	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-133 in pregnant women, women who may possibly be pregnant is not recommended. [Rhubarb (uterotonic action and congestive action on the intra-pelvic organs), anhydrous Mirabilitum (uterotonic action).
- (2) TJ-133 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-133 may be excreted in breast milk and induce diarrhea in nursing infants.]

**6. Pediatric Use**

The safety of TJ-133 in children has not been established.  
[Insufficient clinical data]

**7. Other Precautions**

TJ-133 contains anhydrous Mirabilitum. Caution should be exercised when continuous treatment with TJ-133 is given to patients who need limited salt-intake therapeutically.

**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