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Standard Commodity Classification No. of Japan
875200

■ 33 ■

- Kampo-preparation-

TSUMURA Daiobotampito 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.	(61AM)3321
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 Daiobotampito extract granules (hereafter TJ-33) contains 3.5 g of a dried extract of the following mixed crude drugs.	
	JP Benincasa Seed 6.0 g JP Peach Kernel 4.0 g JP Moutan Bark 4.0 g JP Rhubarb 2.0 g JP Anhydrous Sodium Sulfate 1.8 g (JP: The Japanese Pharmacopoeia)	
Description	Inactive ingredients	JP Light Anhydrous Silicic Acid JP Magnesium Stearate JP Lactose Hydrate
	Dosage form	Granules
	Color	Yellow-brown
	Smell	Characteristic smell
	Taste	Sour and characteristic
	ID code	TSUMURA/33

INDICATIONS

TJ-33 is indicated for the relief of the following symptoms of those patients with a comparatively strong constitution and lower abdominal pain who are likely to have constipation: Menstrual irregularity, dysmenorrhea, constipation, and hemorrhoid

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-33 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-33 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-33 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-33 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-33 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-33 in pregnant women, women who may possibly be pregnant is not recommended. [Rhubarb (uterotonic action and congestive action on the intra-pelvic organs), Anhydrous Sodium Sulfate (uterotonic action), Peach Kernel, Moutan Bark contained in TJ-33 may cause premature birth or abortion.]
- (2) TJ-33 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-33 may be excreted in breast milk and induce diarrhea in nursing infants.]

6. Pediatric Use

The safety of TJ-33 in children has not been established.
[Insufficient clinical data]

7. Other Precautions

TJ-33 contains Anhydrous Sodium Sulfate. Caution should be exercised when continuous treatment with TJ-33 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:

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