Revised: August 2017 (7th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Daiobotampito Extract Granules

< Daiobotampito >

Storage
Store at room temperature in a tight container. [See the “Precaution for handling” section.]

Expiration date
Daiobotampito should be used before the expiration date indicated on the label and the package.

Approval No.	(61AM) 3680
Date of listing in the NHI reimbursement price	July 1988
Date of initial marketing in Japan	July 1988

DESCRIPTION

Composition	7.5 g of TEIKOKU Daiobotampito Extract Granules contains 2.32 g of a dried water extract of the following mixed crude drugs. JP Rhubarb ---------- 2.0 g JP Moutan Bark ---------- 4.0 g JP Peach Kernel ---------- 4.0 g JP Sodium Sulfate Hydrate ------ 4.0 g JP Benincasa Seed ---------- 6.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
Description	Dosage form	Granules
	Color	Light yellowish brown
	Smell	Slightly characteristic smell
	Taste	Salty and slightly bitter
	ID code	TEIKOKU 33

INDICATIONS

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

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Daiobotampito Extract Granules three times daily before meals.

The dosage may be adjusted according to the patient’s age, body weight, and symptoms.

PRECAUTIONS

1. Careful Administration (Daiobotampito 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 this product 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 this product 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 this product 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

This product 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 this product in pregnant women, women who may possibly be pregnant is not recommended. [Rhubarb (uterotonic action and congestive action on the intrapelvic organs), Sodium Sulfate (uterotonic action), Peach Kernel, Moutan Bark contained in this product may cause premature birth or abortion.]

(2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in breast milk and induce diarrhea in nursing infants.]

6. Pediatric Use

The safety of this product in children has not been established. [Insufficient clinical data.]

7. Other Precautions

This product contains Sodium Sulfate. Caution should be exercised when continuous treatment with this product is given to patients who need limited salt-intake therapeutically.

PRECAUTIONS FOR HANDLING

1.This product should not be stored in direct rays and should be stored in a cool place with, if possible, little humidity.

2.Since it is hygroscopic property, this product should not be stored in humid places after opening.

PACKAGING

Bottles of 500 g

Boxes of 2.5 g× 42 packets

Boxes of 2.5 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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