Revised: March 2013 (5th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Keihito Extract Granules for Ethical Use

<keihito>

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.	(62AM)576
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

Composition	7.5 g of TSUMURA Keihito extract granules contains 4.75 g of a dried extract of the following mixed crude drugs. JP Atractylodes Lancea Rhizome ..... 4.0 g JP Poria Sclerotium …..……. 4.0 g JP Dioscorea Rhizome ..... 3.0 g JP Ginseng ..... 3.0 g JP Nelumbo Seed ..... 3.0 g JP Crataegus Fruit …….... 2.0 g JP Alisma Rhizome ……..… 2.0 g JP Citrus Unshiu Peel ……...…... 2.0 g JP Glycyrrhiza ……..... 1.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate Sucrose Esters of Fatty Acids
Description	Dosage form	Granules
	Color	Light brown
	Smell	Characteristic smell
	Taste	Sour and slightly bitter
	ID code	TSUMURA/128

INDICATIONS

TSUMURA Keihito Extract Granules (hereafter TJ-128) is indicated for the relief of the following symptoms of those patients who are thin and have a bad complexion, anorexia, and tendency to diarrhea:

Weak digestive system, chronic gastroenteritis, dyspepsia, and diarrhea

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. Important Precautions

(1) When TJ-128 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) Since TJ-128 contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc., and if any abnormality is observed, administration should be discontinued.

(3) When TJ-128 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.

2. Drug Interactions

Precautions for coadministration (TJ-128 should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Glycyrrhiza (2) Preparations containing glycyrrhizinic acid or glycyrrhizinates	Pseudoaldosteronism is likely to occur. Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".)	Since glycyrrhizinic acid has an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested.

3. Adverse Reactions

TJ-128 has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

(1) Clinically significant adverse reactions

1) Pseudoaldosteronism: Pseudoaldosteronism such as hypokalemia, increased blood pressure, retention of sodium/body fluid, edema, increased body weight, etc. may occur. The patient should be carefully monitored (measurement of serum potassium level, etc.), and if any abnormality is observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

2) Myopathy: Myopathy may occur as a result of hypokalemia. The patient should be carefully monitored, and if any abnormality such as weakness, convulsion/paralysis of limbs, etc. are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

(2) Other adverse reactions

	Incidence unknown
Hypersensitivity Note 1)	Rash, Urticaria, etc.

Note 1) If such symptoms are observed, administration should be discontinued.

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-128 in pregnant women has not been established. Therefore, TJ-128 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-128 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:

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

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