

Revised: March 2013 (6th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation-

TSUMURA Nijutsuto Extract Granules for Ethical Use

<nijutsuto>

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)3264
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 Nijutsuto extract granules (hereafter TJ-88) contains 5.0 g of a dried extract of the following mixed crude drugs.	
		JP Pinellia Tuber 4.0 g JP Atractylodes Lancea Rhizome 3.0 g JP Clematis Root 2.5 g JP Scutellaria Root 2.5 g JP Cyperus Rhizome 2.5 g JP Citrus Unshiu Peel 2.5 g JP Atractylodes Rhizome 2.5 g JP Poria Sclerotium 2.5 g JP Glycyrrhiza 1.0 g JP Ginger 1.0 g Arisaema Tuber 2.5 g Aralia Root 2.5 g (JP: The Japanese Pharmacopoeia)
Description	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate Sucrose Esters of Fatty Acids
	Dosage form	Granules
	Color	Light yellow-brown
	Smell	Characteristic smell
	Taste	Acrid and bitter
	ID code	TSUMURA/88

INDICATIONS

Frozen shoulder

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-88 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-88 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-88 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-88 should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Glycyrrhiza	Pseudoaldosteronism is likely to occur.	Since glycyrrhizic 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.
(2) Preparations containing glycyrrhizinic acid or glycyrrhizinates	Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".)	

3. Adverse Reactions

TJ-88 has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

Clinically significant adverse reactions

- (1) **Interstitial pneumonia:** If fever, cough, dyspnea, abnormal pulmonary sound, etc. are observed, administration of TJ-88 should be discontinued, and examinations such as X-ray or chest CT should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken.
- (2) **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.
- (3) **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.
- (4) **Hepatic dysfunction and jaundice:** Hepatic dysfunction and/or jaundice with elevation of AST (GOT), ALT (GPT), Al-P and γ -GTP or other symptoms may occur. The patient should be carefully monitored for abnormal findings. Administration should be discontinued and appropriate therapeutic measures should be taken, if abnormalities are observed.

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-88 in pregnant women has not been established. Therefore, TJ-88 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-88 in children has not been established.
[Insufficient clinical data]

PACKAGING

Bottles of 500 g
2.5 g \times 42 packets
2.5 g \times 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