Revised: August 2009 (5th version)

Standard Commodity Classification No. of Japan
875200

■22■

- Kampo-preparation-

TSUMURA Shofusan 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)3270
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 Shofusan extract granules (hereafter TJ-22) contains 4.0 g of a dried extract of the following mixed crude drugs. JP Rehmannia Root …… 3.0 g JP Gypsum ..... 3.0 g JP Japanese Angelica Root ..... 3.0 g JP Burdock Fruit ..... 2.0 g JP Atractylodes Lancea Rhizome ..... 2.0 g JP Saposhnikovia Root ..... 2.0 g JP Akebia Stem ..... 2.0 g JP Sesame …… 1.5 g JP Anemarrhena Rhizome ……. 1.5 g JP Glycyrrhiza ……... 1.0 g JP Sophora Root …… 1.0 g JP Schizonepeta Spike ……... 1.0 g Cicada Slough……...…….. 1.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Light Anhydrous Silicic Acid JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Grayish-brown
	Smell	Characteristic smell
	Taste	Slightly sweet and bitter
	ID code	TSUMURA/22

INDICATIONS

Chronic dermatosis(eczema, urticaria, athlete's foot, miliaria, pruritus) with much exudation and severe itching

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-22 should be administered with care in the following patients.)

(1) Patients with a weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, soft feces, diarrhea, etc. may occur.]

(2) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]

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

2. Important Precautions

(1) When TJ-22 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-22 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-22 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.

3. Drug Interactions

Precautions for coadministration (TJ-22 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.

4. Adverse Reactions

TJ-22 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, Redness, Pruritus, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Soft feces, Diarrhea, etc.

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

5. Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

6. Use during Pregnancy, Delivery or Lactation

The safety of TJ-22 in pregnant women has not been established. Therefore, TJ-22 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.

7. Pediatric Use

The safety of TJ-22 in children has not been established. [Insufficient clinical data]

8. Other Precautions

Symptoms may be aggravated in dermatosis with dry affected areas.

PHARMACOLOGY

1. Antihistaminic effects

Oral administration of Shofusan in dogs inhibited histamine-induced intracutaneous responses (comparison of the distended site diameter) [1].

2. Anti-allergic effects

Oral administration of Shofusan inhibited antigen application of (DNFB)-induced diphasic dermal reactions (edema) in mice that had been sensitized with anti-DNP monoclonal IgE antibody[2].

3. Effective mechanism

Shofusan shows pharmacological effects via the following actions:

Anti-inflammatory effects

Shofusan inhibited production of active oxygen (O_2^-, H_2O_2, OH·) in human-derived neutrophil and cell-free xanthine-xanthine oxidase systems. Furthermore, it decreased concentration of Ca^{2+} in the neutrophil (*in vitro*) [3].

PACKAGING

Bottles of 500 g and boxes of 5 kg (500 g × 10 bottles)
2.5 g × 42 packets
2.5 g × 189 packets

REFERENCES

1) Okada, K. et al. J. Jpn. Vet. Med. Assoc. 1995, 48(9), p.673.
2) Tsunematsu, N. et al. J. Traditional Med. 1996, 13(1), p.66.
3) Akamatsu, H. et al. Status of traditional Japanese traditional herbal medicine treatment in the dermatological field 5. PHARMAINTERNATIONAL, 1994, p.35.

■ **REQUEST FOR LITERATURE SHOULD BE MADE TO:**
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