Revised: February 2018 (9th version)

Standard Commodity Classification No. of Japan
875200

■104■

- Kampo-preparation-

TSUMURA Shin'iseihaito 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)1127
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 Shin'iseihaito extract granules (hereafter TJ-104) contains 4.5 g of a dried extract of the following mixed crude drugs. JP Gypsum ..... 5.0 g JP Ophiopogon Root ..... 5.0 g JP Scutellaria Root ..... 3.0 g JP Gardenia Fruit ..... 3.0 g JP Anemarrhena Rhizome ..... 3.0 g JP Lilium Bulb ..... 3.0 g JP Magnolia Flower …….. 2.0 g JP Loquat Leaf ……..……. 2.0 g JP Cimicifuga Rhizome ……..…….. 1.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Magnesium Stearate JP Lactose Hydrate
Description	Dosage form	Granules
	Color	Yellow-brown
	Smell	Characteristic smell
	Taste	Bitter
	ID code	TSUMURA/104

INDICATIONS

Nasal obstruction, chronic rhinitis, and empyema

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-104 should be administered with care in the following patients.)

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

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

2. Important Precautions

(1) When TJ-104 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) Long-term administration of a gardenia fruit-containing preparation (usually 5 years or longer) may cause mesenteric phlebosclerosis accompanied by discoloration, edema, erosion, ulceration, and stenosis of the colon. Periodical examinations such as CT scanning and colonoscopy would be desirable in cases of its long-term administration.

(3) When TJ-104 is co-administered 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. Adverse Reactions

TJ-104 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) Interstitial pneumonia: If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of TJ-104 should be discontinued, and examinations such as X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken. Besides, the patient should be advised to discontinue TJ-104 immediately and to make contact with the physician in the event of fever, cough, dyspnea, etc.

2) **Hepatic dysfunction and jaundice**: Hepatic dysfunction and/or jaundice with remarkable 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.

3) **Mesenteric phlebosclerosis**: Mesenteric phlebosclerosis may occur with long-term administration. If symptoms such as abdominal pain, diarrhea, constipation, and abdominal distension repeatedly occur, or if the patient tests positive for fecal occult blood, administration should be discontinued. At the same time, tests such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases.

(2) Other adverse reactions

	Incidence unknown
Hypersensitivity Note 1)	Rash, Redness, Pruritus, Uriticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Soft feces, Diarrhea, 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-104 in pregnant women has not been established. Therefore, TJ-104 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-104 in children has not been established. [Insufficient clinical data.]

PHARMACOLOGY

Mechanisms of action

TJ-104 was suggested to exhibit the pharmacological effects by the following mechanisms of action.

Anti-inflammatory actions

Shin'iseihaito extract granule inhibited the fMLP-induced production of active oxygen in human-derived neutrophils, but did not influence the opsonified zymosan-induced production of active oxygen (*in vitro*) [1].

PACKAGING

Bottles of 500 g
Boxes of 5 kg (500 g bottle × 10)
2.5 g × 42 packets
2.5 g × 189 packets

REFERENCES

1) Matsunaga, S. et al. Pract. Otol. 1992, 85(12), p.1975.

■**REQUEST FOR LITERATURE SHOULD BE MADE TO:**
Consumer Information Services Center
Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan
TEL: 0120-329970 FAX: 03-5574-6610

■**Manufactured and Distributed by:**
Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan