

Revised: February 2018 (12th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Orengedokuto Extract Granules

< Orengedokuto >

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

Approval No.	(61AM) 3678
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987
Date of latest reevaluation	April 2014

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

DESCRIPTION

Composition	7.5 g of TEIKOKU Orengedokuto Extract Granules contains 1.70 g of a dried water extract of the following mixed crude drugs.	
		JP Coptis Rhizome ----- 2.0 g
		JP Phellodendron Bark ----- 2.0 g
		JP Scutellaria Root ----- 3.0 g
		JP Gardenia Fruit ----- 2.0 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	Almost odorless
	Taste	Extremely bitter
	ID code	TEIKOKU 15

INDICATIONS

The following symptoms of those patients with comparatively strong constitution, a touch of hot flushes, redness of face, and a tendency to irritability:

Nose bleeding, hypertension, insomnia, neurosis, gastritis, hangover, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, dizziness, palpitation, eczema or dermatitis, and pruritus cutaneous

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 2.5 g of TEIKOKU Orengedokuto 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 (Orengedokuto should be administered with care in the following patients.)

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) 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 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.

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.

(1) Clinically significant adverse reactions

1) Interstitial pneumonia: If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of this product 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 this product 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), ALP 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)}	Rash, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, etc.

Note) 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 this product in pregnant women has not been established. Therefore, the product 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 this product in children has not been established. [Insufficient clinical data.]

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:

Product Information Unit,
Pharmaceutical Sales & Marketing Dept.
Teikoku Seiyaku Co., Ltd.
6-6 Nihonbashi-kobunacho, Chuo-Ku, Tokyo
103-0024, Japan
Tel 0120-189-567

Manufactured by:

Teikoku Kampo Seiyaku Co., Ltd.
80-11 Kitahara, Donari, Donari-cho, Awa, Tokushima
771-1506, Japan

Distributed by:

Teikoku Seiyaku Co., Ltd.
567, Sanbonmatsu, Higashikagawa, Kagawa
769-2695, Japan