Revised: February 2018 (11th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Unseiin Extract Granules

< Unseiin >

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

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

Approval No.	(61AM) 3692
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

Composition	9.0 g of TEIKOKU Unseiin Extract Granules contains 4.41 g of a dried water extract of the following mixed crude drugs. JP Japanese Angelica Root ------ 3.0 g JP Rehmannia Root ---------- 3.0 g JP Peony Root ---------- 3.0 g JP Cnidium Rhizome ---------- 3.0 g JP Coptis Rhizome ---------- 1.5 g JP Scutellaria Root ---------- 1.5 g JP Gardenia Fruit ---------- 1.5 g JP Phellodendron Bark ---------- 1.5 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
Description	Dosage form	Granules
	Color	Light brown
	Smell	Slightly characteristic smell
	Taste	Bitter
	ID code	TEIKOKU 57

INDICATIONS

The following symptoms of those patients with a sallow complexion and hot flushes:

Menstrual irregularity, dysmenorrhea, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, climacteric disturbance, and neurosis

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 3.0 g of TEIKOKU Unseiin 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 (Unseiin should be administered with care in the following patients.)

(1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc. may occur.]

(2) Patients with anorexia, nausea or vomiting [These 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, etc. are observed, administration of this product 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) **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.

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, Redness, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, 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 3.0 g× 42 packets
Boxes of 3.0 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

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