ID Code	SG-23

October 2005
(1st version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

OHSUGI Tokishakuyakusanryo Extract Granules G

Storage: Store at room temperature. See the section "PRECAUTIONS FOR HANDLING" Expiration date: The expiration date is specified on the container or the outer package.

Approval No.	(61AM) 4811
Date of listing in the NHI reimbursement price	October 1987
Date of initial marketing in Japan	October 1987

DESCRIPTION

(1) The daily dose of this product,7.5 g, contains 4.2 g of the dried extract (Tokishakuyakusanryo extract) from the following mixed crude drugs.
JP Japanese Angelica Root ---------- 3 g
JP Poria Sclerotium ---------- 4 g
JP Cnidium Rhizome ---------- 3 g
JP Atractylodes Rhizome ---------- 4 g
JP Peony Root ---------- 4 g
JP Alisma Tuber ---------- 4 g
(JP: The Japanese Pharmacopeia)
The inactive ingredients contained are Lactose Hydrate, Corn Starch and Magnesium Stearate.

(2) This product is light grayish and dark brown to light grayish brown-colored granules, and smells slightly. It tastes slightly sweet and bitter and the taste remains.
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INDICATIONS

The following symptoms of those patients with comparatively weak constitution, slight oversensitivity to cold, and slight anemia who are easily fatigued and sometimes have lower abdominal pain, dull headache, dizziness, shoulders stiffness, buzzing in the ears, palpitation,etc.:
Menstrual irregularity, abnormal menstruation, menses painful, climacteric disturbance, disorders fatigue before/after childbearing or abortion (anemia, fatigue and malaise, dizziness, edema), dizziness, dull headache, shoulder stiffness, low back pain, cold feeling in the lower limbs and waist, chilblain, edema and spots

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 g/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

PRECAUTIONS

(1) Careful Administration (Tokishakuyakusanryo 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) When this product is coadministered with other Kampo-products (Japanese traditional herbal medicines), etc., attention should be paid to the duplication of the contained crude drugs.

(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.

	Incidence Unknown
Hypersensitivity Note 1)	Rash, pruritus, etc.
Hepatic	Abnormality of hepatic function [increased AST (GOT), ALT (GPT) levels, etc.]
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, 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 this product in pregnant woman 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

- Store at dry and cool place, protected from direct sunlight.
- Since this product contains natural crude drugs, some differences may be noted in the color or taste, etc. However, there is no change in the effect.

PACKAGING

500g
735g (2.5g x 294 packets),
210g (2.5g x 84 packets)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., LTD.
1-8-6, Yamasaka, Higashisumiyoshi-ku, Osaka 546-0035
050-3776-0358