ID Code	FC 25

October 2005
(2nd version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

JUNKOU Keishibukuryoganryo FC Extract Fine Granules for Ethical Use

(Keishibukuryogan)

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

Approval No.	(61AMY) 0366
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986

DESCRIPTION

(1) The daily dose of this product, 4.50 g contains 2.25 g of the dried extract (Keishibukuryoganryo) from the following mixed crude drugs.

JP Cinnamon Bark ---------- 4.00 g
JP Peach Kernel ---------- 4.00 g
JP Poria Sclerotium ---------- 4.00 g
JP Peony Root ---------- 4.00 g
JP Moutan Bark ---------- 4.00 g
(JP: The Japanese Pharmacopeia)

The inactive ingredients contained are Corn Starch and Lactose Hydrate.

(2) This product is brown-colored fine granules, smells slightly, and tastes slightly sweet.
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INDICATIONS

The following symptoms of those patients with comparatively strong constitution who sometimes have lower abdominal pain, shoulder stiffness, dull headache, dizziness, feeling of hot flushes with lower limbs being susceptible to cold, etc.: Menstrual irregularity, abnormal menstruation, menses painful, climacteric disturbance, automatic imbalance syndrome peculiar to women resembling climacteric disturbance, shoulder stiffness, dizziness, dull headache, contusion, chilblain, and spots

DOSAGE AND ADMINISTRATION

The usual adult dose is 4.5 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 (Keishibukuryoganryo should be administered with care in the following patients.)

Patients with an extremely 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) 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.

1) Clinically significant adverse reactions

Hepatic dysfunction and jaundice: Hepatic dysfunction with elevation of AST(GOT), ALT(GPT), Al-P and γ - GTP level, and/ or jaundice 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.

2) Other adverse reactions

	Incidence Unknown
Hypersensitivity Note 1)	Rash, Redness, Pruritus, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, 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

Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [Peach Kernel, Moutan Bark contained in this product may cause premature birth or abortion.]

(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

126 g (1.5 g 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