ID Code	FC 15

April 2014
(5th version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

JUNKOU Orengedokuto FC Extract Fine Granules for Ethical Use

(Orengedokuto)

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) 0374
Date of listing in the NHI reimbursement price	October 1986
Date of initial marketing in Japan	October 1986
Date of latest reevaluation	April 2014

DESCRIPTION

(1) The daily dose of this product, 4.50 g, contains 1.25 g of the dried extract (Orengedokuto extract) from the following mixed crude drugs.
JP Coptis Rhizome ---------- 2.00 g
JP Scutellaria Root ---------- 3.00 g
JP Phellodendron Bark ---------- 2.00 g
JP Gardenia Fruit ---------- 2.00 g
(JP: The Japanese Pharmacopeia)
The inactive ingredients contained are Corn Starch and Lactose Hydrate.

(2) This product is yellowish brown-colored fine granules, smells slightly, tastes extremely bitter.
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INDICATIONS

The following symptoms of those patients who have ruddy face with comparatively strong constitution, a touch of hot flushes, and a tendency to irritability:
Nose bleeding, hypertension,insomnia, neurosis, gastritis, alcoholic hangover,climacteric disturbance and
automatic imbalance syndrome, peculiar to women resembling climacteric disturbance, dizziness,and palpitation,eczema or dermatitis and pruritus cutaneous.

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 (Orengedokuto 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

① **Interstitial Pneumonia**: If fever, cough, dyspnea, abnormal pulmonary sound (fine crackle), etc. are observed, administration of this product should be discontinued, and examination such as chest X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones should be 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), 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 re-ported in some cases.

2) Other adverse reactions

	Incidence Unknown
Hypersensitivity Note 1)	Rash, Urticaria, 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 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

- 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