

October 2005
(2nd version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

JUNKOU Saikokaryukotsuboreito FC Extract Fine Granules for Ethical Use

(Saikokaryukotsuboreito)

Storage: Store at room temperature. See the section "PRECAUTIONS FOR HANDLING" Expiration date: The expiration date is indicated on the outer package.
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Approval No.	(61AMY) 0369
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, 6.00 g, contains 4.00 g of the dried extract (Saikokaryukotsuboreito extract) from the following mixed crude drugs.

JP Bupleurum Root -----	5.00 g
JP Longgu -----	2.50 g
JP Pinellia Tuber -----	4.00 g
JP Oyster Shell -----	2.50 g
JP Poria Sclerotium -----	3.00 g
JP Ginger -----	1.00 g
JP Cinnamon Bark -----	3.00 g
JP Rhubarb -----	1.00 g
JP Jujube -----	2.50 g
JP Scutellaria Root -----	2.50 g
JP Ginseng -----	2.50 g

(JP: The Japanese Pharmacopeia)

The inactive ingredients contained are Corn Starch and Lactose Hydrate.

(2) This product is brown-colored fine granules, smells uniquely, and tastes slightly bitter initially and slightly hot later.
ID Code: FC 12

INDICATIONS

The following symptoms of those patients with palpitation and insomnia who have mental instability:

Symptoms associated with hypertension (palpitation, anxiety, and insomnia), neurosis, climacteric neurosis, and night cry in children

DOSAGE AND ADMINISTRATION

The usual adult dose is 6.0 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 (Saikokaryukotsuboreito should be administered with care in the following patients.)

- 1) Patient with diarrhea, or soft feces [These symptoms may be aggravated]
- 2) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, abdominal pain, diarrhea, etc. may occur.]
- 3) 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. Particular attention should be paid to coadministration with other products containing Rhubarb.
- 3) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

(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, 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, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, 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

- 1) Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in this product may cause premature birth or abortion.]
- 2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in breast milk and induce diarrhea in nursing infants]

(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

168 g (2.0 g x 84 packets)

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., Ltd.
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