ID Code	FC 10

October 2005
(2nd version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

JUNKOU Saikokeishito FC Extract Fine Granules for Ethical Use

(Saikokeishito)

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) 0368
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 3.35 g of the dried extract (Saikokeishito extract) from the following mixed crude drugs.

JP Bupleurum Root ---------- 5.00 g
JP Ginseng ---------- 2.00 g
JP Pinellia Tuber---------- 4.00 g
JP Jujube ---------- 2.00 g
JP Cinnamon Bark ---------- 2.50 g
JP Glycyrrhiza ---------- 1.50 g
JP Peony Root---------- 2.50 g
JP Ginger ---------- 1.00 g
JP Scutellaria Root ---------- 2.00 g
(JP: The Japanese Pharmacopeia)

The inactive ingredients contained are Corn Starch and Lactose Hydrate.

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

Gastroenteritis with abdominal pain, common cold with slight fever, rigor, headache, nausea,etc., and symptoms in the latter stage of common cold

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) 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) Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc., and if any abnormality is observed, administration should be discontinued.
3) 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.

(2) Drug Interactions

Precautions for coadministration (Saikokeishito should be administered with care when coadministered with the following drugs.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
(1) Preparations containing Glycyrrhiza (2) Preparations containing glycyrrhizinic acid or glycyrrhizinates	Pseudoaldosteronism is likely to occur. Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".)	Since glycyrrhizinic acid has an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested.

(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 **Pseudoaldosteronism**: Pseudoaldosteronism such as hypokalemia, increased blood pressure, retention of sodium/body fluid, edema, increased body weight, etc. may occur. The patient should be carefully monitored (measurement of serum potassium level, etc.) and if any abnormality is observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

③ **Myopathy**: Myopathy may occur as a result of hypokalemia. The patient should be carefully monitored, and if any abnormality such as weakness, convulsion/paralysis of limbs, etc. are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

④ **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	Diarrhea, Constipation, Dyspepsia, etc.
Urinary Note 2)	Pollakiuria, Micturition pain, Hematuria, Feeling of residual urine, Cystitis-like symptoms, etc.

Note 1) If such symptoms are observed, administration should be discontinued.

Note 2) Since these symptoms may occur, the patient should be carefully monitored, and if abnormalities observed, administration of this product should be discontinued and appropriate measures taken.

(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]

(7) Other precautions

Adverse reaction of interstitial pneumonia has been reported frequently with a similar prescription “Shosaikoto” in the case of combined use with interferone-α

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.
1-8-6, Yamasaka, Higashisumiyoshi-ku, Osaka 546-0035
050-3776-0358