Revised：October 2022 (1st version)

Standard Commodity Classification No. of Japan
875200

-Kampo product-

FC41

JUNKOU Hochuekkito

FC Extract Fine Granules for Ethical Use

FC41T

JUNKOU Hochuekkito

FC Tablets for Ethical Use

(Hochuekkito)

	Approval No.	Date of Initial Marketing in Japan
Fine Granules	16100AMY00380000	October 1986
Tablets	16200AMY00036000	March 2015

Storage：Store at room temperature

Shelf Life：3 years

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	JUNKOU Hochuekkito FC Extract Fine Granules for Ethical Use	JUNKOU Hochuekkito FC Tablets for Ethical Use
Active ingredient	The daily dose of this product, 7.5 g, contains 4.9 g of the dried extract (Hochuekkito extract) from the following mixed crude drugs.	The daily dose of this product, 18 tablets, contains 4.9 g of the dried extract (Hochuekkito extract) from the following mixed crude drugs.
	JP Ginseng 4 g JP Atractylodes Rhizome 4 g JP Astragalus Root 4 g JP Japanese Angelica Root 3 g JP Citrus Unshiu Peel 2 g JP Jujube 2 g JP Bupleurum Root 2 g JP Glycyrrhiza 1.5 g JP Ginger 0.5 g JP Cimicifuga Rhizome 1 g JP ：Japanese Pharmacopoeia	
Excipients	Corn Starch and Lactose Hydrate	Corn Starch, Lactose Hydrate, Talc and Magnesium Stearate

3.2 Product Description

Brand name	JUNKOU Hochuekkito FC Extract Fine Granules for Ethical Use	JUNKOU Hochuekkito FC Tablets for Ethical Use		
Dosage form	Fine granules	Tablets		
Tone	Yellowish brown-colored fine granules	Yellowish brown-colored tablets		
Smells	Uniquely	-		
Tastes	Slightly bitter initially and slightly sweet later	-		
Form	-	Front	Back	Side
				
Diameter	-	About 10 mm		
Thickness	-	About 5.5 mm		
Weight	-	About 417 mg		
ID Code	ＦＣ４１	ＦＣ４１Ｔ		

4. INDICATIONS

The following symptoms in patients who have easily fatigued, have lack of energy, with weak gastrointestinal functions:
Weak constitution, fatigue, malaise, weakness after illness, anorexia, night sweats

6. DOSAGE AND ADMINISTRATION

< JUNKOU Hochuekkito FC Extract Fine Granules for Ethical Use >

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.

< JUNKOU Hochuekkito FC Tablets for Ethical Use >

The usual adult dose is 18 tablets/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.

8. IMPORTANT PRECAUTIONS

8.1 When this product is used, the patient's "SHO" (constitution/symptoms) should be taken into consideration. The patient's progress should be carefully monitored, and if no improvement in symptoms or findings is observed, continuous administration should be avoided.

8.2 Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc. [See Sections 10.2, 11.1.2, 11.1.3]

8.3 When this product is used in combination with other Kampo products, etc., attention should be paid to the duplication of the contained crude drugs.

SHO: The term "SHO" refers to a particular pathological status of a patient evaluated by the Kampo diagnosis, and is patterned according to the patient's constitution, symptoms, etc. Kampo products should be used after confirmation that it is suitable for the identified "SHO" of the patient.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.5 Pregnant Women

This product should be used in pregnant women or women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

9.6 Breast-feeding Women

Considering the therapeutic benefits and the benefits of breastfeeding, continuation or discontinuation of breastfeeding should be considered.

9.7 Pediatric Use

No clinical studies have been conducted in children.

9.8 Geriatric Use

Since the physiological functions are generally decreased in elderly patients, careful supervision is recommended; measures such as reducing the dose may be considered.

10. INTERACTIONS

10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Glycyrrhiza-containing preparations Shakuyakukanzoto Yokukansan Rikkunshito, etc. Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/ L-cysteine Monoammonium Glycyrrhizinate/Glycine/ DL-Methionine combination tablets, etc. [See Sections 8.2, 11.1.2, 11.1.3]	Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur.	Since glycyrrhizic acid has an accelerating effect on potassium excretion in the renal tubules, an acceleration of decrease in the serum potassium level has been suggested.

11. ADVERSE REACTIONS

The following adverse reactions may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

11.1 Clinically Significant Adverse Reactions

11.1.1 Interstitial pneumonia (frequency unknown)

If cough, dyspnea, pyrexia, abnormal lung sound, etc. are observed, administration of this product should be discontinued, and examinations such as chest X-ray and chest CT scan should be performed immediately, and appropriate measures such as administration of corticosteroid should be taken. In addition, patients should be advised to discontinue administration of this product and contact the physician immediately if cough, dyspnea, or pyrexia, etc. occur.

11.1.2 Pseudoaldosteronism (frequency unknown)

Pseudoaldosteronism such as hypokalaemia, blood pressure increased, retention of sodium/body fluid, edema, and body weight gain may occur. Patients should be carefully monitored (e.g., measurement of serum potassium levels), and if any abnormalities are observed, administration should be discontinued, and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

11.1.3 Myopathy (frequency unknown)

Myopathy may occur as a result of hypokalaemia. Patients should be carefully monitored, and if any abnormalities such as feelings of weakness, muscle cramp in extremities, or paralysis are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

11.1.4 Hepatic impairment, jaundice (frequency unknown)

Hepatic impairment and/or jaundice with marked elevations of AST, ALT, Al-P, γ-GTP, etc. may occur.

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, urticaria, etc.
Gastrointestinal	Anorexia, epigastric distress, nausea, diarrhea, etc.

15. OTHER PRECAUTIONS

15.1 Information Based on Clinical Use

Eczema or dermatitis may be aggravated.

20. PRECAUTIONS FOR HANDLING

20.1 To maintain the quality of the product, avoid moisture as much as possible and store in a cool place, away from direct sunlight.

20.2 Avoid moisture, especially after opening, and handle with care.

20.3 Since this product is made from crude drugs, the color of the product may vary.

22. PACKAGING

< JUNKOU Hochuekkito FC Extract Fine Granules for Ethical Use >
210 g （2.5 g × 84 packets） ［Sachet］

< JUNKOU Hochuekkito FC Tablets for Ethical Use >
504 tablets （3 tablets × 168 packets） ［Sachet］

24. REFERENCE REQUEST AND CONTACT INFORMATION

Dep. of PMS Information,
Ohsugi Pharmaceutical Co., Ltd.
1-8-6, Yamasaka, Higashisumiyoshi-ku, Osaka 546-0035
06-6629-9058

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Marketing Authorization Holder

Kohwayakutuu Inc.
1000-37, Enmyocho, Kashiwara-shi, Osaka 582-0027

26.2 Publisher

Ohsugi Pharmaceutical Co., Ltd.
1-1-2, Tennojichominami Abeno-ku, Osaka 545-0002