Prepared：June 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

-Kampo product-

JUNKOU Kamishoyosan
FC Tablets for Ethical Use

(Kamishoyosan)

Storage：Store at room temperature

Shelf Life：3 years

	Approval No.	Date of Initial Marketing in Japan
Tablets	16200AMY00027000	June 2023

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	JUNKOU Kamishoyosan FC Tablets for Ethical Use	
Active ingredient	The daily dose of this product, 18 tablets, contains 4.75 g of the dried extract (Kamishoyosan extract) from the following mixed crude drugs.	
	JP Japanese Angelica Root	3 g
	JP Peony Root	3 g
	JP Atractylodes Rhizome	3 g
	JP Poria Sclerotium	3 g
	JP Bupleurum Root	3 g
	JP Moutan Bark	2 g
	JP Gardenia Fruit	2 g
	JP Glycyrrhiza	2 g
	JP Ginger	1 g
	JP Mentha Herb	1 g
	JP ：Japanese Pharmacopoeia	
Excipients	Corn Starch, Lactose Hydrate, Talc and Magnesium Stearate	

3.2 Product Description

Brand name	JUNKOU Kamishoyosan FC Tablets for Ethical Use		
Dosage form	Tablets		
Tone	Grayish-brown to brown or yellowish-brown colored tablets		
Form	Front	Back	Side
			
Diameter	About 9 mm		
Thickness	About 5.2 mm		
Weight	About 333 mg		
ID Code	ＦＣ２４Ｔ		

4. INDICATIONS

The following symptoms in patients who have women with a weak constitution, stiff shoulder muscles, and who are easily fatigued, or have psychoneurotic symptoms such as mental anxiety, and sometimes constipation:

Sensitivity to cold, weak constitution, menstrual irregularity, dysmenorrhea, climacteric disturbance, menopausal and female climacteric states

6. DOSAGE AND ADMINISTRATION

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, 11.1.1, 11.1.2]

8.3 Prolonged administration of preparations containing Gardenia Fruit (for more than 5 years in most cases) may cause mesenteric phlebosclerosis with pigmentation, edema, erosion, ulceration, and stenosis of the colon. In the case of long-term administration, periodic examinations such as CT and colonoscopy are recommended. [See Section 11.1.4]

8.4 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

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with an extremely weak gastrointestinal tract

Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc. may occur.

9.1.2 Patients with anorexia, nausea, or vomiting

These symptoms may be aggravated.

9.5 Pregnant Women

It is not recommended to administer this product to pregnant women or women who may possibly be pregnant. Moutan Bark contained in this product may cause premature birth or miscarriage.

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 Hochuekkito Yokukansan, 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, 11.1.1, 11.1.2]	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 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]

11.1.2 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]

11.1.3 Hepatic impairment, jaundice (frequency unknown)

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

11.1.4 Mesenteric phlebosclerosis (frequency unknown)

Mesenteric phlebosclerosis may occur with long-term administration of this product. If abdominal pain, diarrhea, constipation, abdominal distension, etc. are repeatedly observed, or if fecal occult blood test is positive, administration should be discontinued, and examinations such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases. [See Section 8.3]

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, redness, pruritus, etc.
Gastrointestinal	Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, etc.

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

504 tablets （6 tablets × 84 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