

- Kampo product -

**JUNKOU Shakuyakukanzoto FC Extract Granules for Ethical Use**  
(Shakuyakukanzoto)

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) 0414 |
| Date of listing in the NHI<br>reimbursement price | October 1986 |
| Date of initial marketing in Japan                | October 1986 |
| Date of latest reevaluation                       | April 2014   |

**CONTRAINDICATIONS (This product is contraindicated in the following patients.)**

1. Patients with aldosteronism
  2. Patients with myopathy
  3. Patients with hyperkalemia
- [1-3: These diseases or symptoms may be aggravated]

**DESCRIPTION**

- (1) The daily dose of this product, 4.50 g contains 2.00 g of the dried extract (Shakuyakukanzoto extract) from the following mixed crude drugs.

JP Peony Root ----- 6.00 g

JP Glycyrrhiza ----- 6.00 g

(JP: The Japanese Pharmacopeia)

Inactive ingredients contained are Corn Starch and Lactose Hydrate.

- (2) This product is brown-colored fine granules, smells slightly, and tastes sweet.  
ID Code: FC 68

**INDICATIONS**

The relief of pain, myalgia or arthralgia, gastric pain and abdominal pain accompanied by sudden muscle spasms

**DOSAGE AND ADMINISTRATION**

The usual adult dose is 4.5 g/day orally in 2 or 3 divided doses before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

**(Precautions on Dosage and Administration)**

The duration of administration of this product should be limited to the minimum period required for the treatment of the patient's condition.

**PRECAUTIONS****(1) Careful Administration ( Shakuyakukanzoto should be administered with care in the following patients.)**

Elderly patients (Refer to the section "Use in the Elderly" )

**(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) 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.

**(3) Drug Interactions**

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

| Drugs   | Signs, Symptoms, and Treatment   | Mechanism and Risk Factors  |
|---|--|---|
| (1) Preparations containing Glycyrrhiza                           | 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 and diuretics have an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested. |
| (2) Preparations containing glycyrrhizinic acid or glycyrrhizates |  |   |
| (3) Loop diuretics<br>Furosemide<br>Ethacrynic acid               |  |   |
| (4) Thiazide diuretics<br>Trichloromethiazide                     |  |   |

#### (4) 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 cough, dyspnea, fever, abnormal pulmonary sound, etc. are observed, administration of this product should be discontinued, and examination such as X-ray or chest CT should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken.

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 **Congestive heart failure, ventricular fibrillation, ventricular tachycardia (including Torsades de Pointes):** The possibility that congestive heart failure, ventricular fibrillation, ventricular tachycardia (including Torsades de Pointes) may occur cannot be ruled out, and the patient should be carefully monitored (measurement of serum potassium levels, etc.). If any abnormal findings such as palpitations, breathlessness, malaise, dizziness, syncope, etc. are observed, administration of this product should be discontinued and appropriate therapeutic measures taken.

④ **Myopathy:** As a result of hypokalemia, myopathy and rhabdomyolysis may occur. If weakness, muscle weakness, myalgia, convulsion/paralysis of limbs, increased CK(CPK), increased blood/urinary myoglobin are observed, administration should be discontinued and appropriate measures such as administration of potassium preparation should be taken.

⑤ **Hepatic dysfunction and jaundice:** Hepatic dysfunction, with extremely elevation of AST(GOT), ALT(GPT), Al-P and  $\gamma$ -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

|                                    | <b>Incidence Unknown</b>         |
|------------------------------------|----------------------------------|
| <b>Hypersensitivity</b><br>Note 1) | Rash, Redness, Pruritus, etc.    |
| <b>Gastrointestinal</b>            | Nausea, Vomiting, Diarrhea, etc. |

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

#### (5) Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

#### (6) 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.

#### (7) 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, Higashiumiyoshi-ku, Osaka 546-0035  
050-3776-0358