

October 2005  
(2nd version)

Standard Commodity Classification No. of Japan
875200

- Kampo product -

## JUNKOU Shimotsuto FC Extract Fine Granules for Ethical Use

(Shimotsuto)

<p>Storage: Store at room temperature. See the section "PRECAUTIONS FOR HANDLING" Expiration date: The expiration date is indicated on the outer package.</p>
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Approval No.	(61AMY) 0415
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, 7.50 g, contains 4.20 g of the dried extract (Shimotsuto extract) from the following mixed crude drugs.

JP Japanese Angelica Root -----	4.00 g
JP Cnidium Rhizome -----	4.00 g
JP Rehmannia Root -----	4.00 g
JP Peony Root -----	4.00 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 bitter initially and slightly sweet later.

ID Code: FC 71

### INDICATIONS

The following symptoms of those patients with dry skin and a sallow complexion without gastrointestinal disorder:  
Recovery from fatigue after childbearing or abortion, menstrual irregularity, oversensitivity to cold, childblain, spots, and automatic imbalance syndrome peculiar to women resembling climacteric disturbance

### DOSAGE AND ADMINISTRATION

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.

### PRECAUTIONS

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

- 1) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]
- 2) Patients with anorexia, nausea or vomiting [These 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.

### (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.

	Incidence Unknown
<b>Gastrointestinal</b>	Anorexia, Epigastric distress, Nausea, Vomiting, Diarrhea, etc.

### (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]

### 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

210 g (2.5 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