

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ04196000
Date of Initial Marketing in Japan	Nov. 1986

Kampo product

JPS Saikokaryukotsuboreito Extract Granules for Ethical Use

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Product Name	JPS Saikokaryukotsuboreito Extract Granules for Ethical Use	
Active Ingredients	JP Bupleurum Root	5.0 g
	JP Pinellia Tuber	4.0 g
	JP Poria Sclerotium	3.0 g
	JP Cinnamon Bark	3.0 g
	JP Scutellaria Root	2.5 g
	JP Jujube	2.5 g
	JP Ginger	0.8 g
	JP Ginseng	2.5 g
	JP Longgu	2.5 g
	JP Oyster Shell	2.5 g
	JP Rhubarb	1.0 g
	7.5 g/day of this product contains 4.1 g of a dried Saikokaryukotsuboreito extract of the above mixed crude drugs.	
Inactive Ingredients	Mg Stearate, Sucrose Esters of Fatty Acids, Lactose Hydrate	

3.2 Product Description

Dosage Form	Granules
Color	Light brown
Smell	Characteristic smell
Taste	Slightly bitter
ID Code	J-12

4. INDICATIONS

The following symptoms in patients with mental anxiety, palpitation, insomnia, etc.:

Concomitant symptoms of hypertension (palpitation, anxiety, insomnia), neurotic disorder, climacteric neurosis, and sleep terror disorder in children

6. DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5 g/day orally in 2 or 3 divided doses before or between meals. The dosage may be adjusted according to the patient's age and 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 When this product is used in combination with other Kampo products, etc., attention should be paid to the duplication of the contained crude drugs. Special attention should be paid to concomitant use with preparations containing Rhubarb.

8.3 Since there are individual differences in the cathartic action of Rhubarb, caution should be exercised with respect to dosage and administration.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACK GROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with diarrhea, loose stools

These symptoms may be aggravated.

9.1.2 Patients with an extremely weak gastrointestinal tract

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

9.1.3 Patients with extremely weakened constitution

Adverse reactions are likely to occur, and the 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. There is a risk of premature birth or miscarriage due to the uterotonic action and hyperemic action of the pelvic organs of Rhubarb contained in this product.

9.6 Breast-feeding Women

Considering the therapeutic benefits and the benefits of breastfeeding, continuation or discontinuation of breastfeeding should be considered. Anthraquinone derivatives in Rhubarb contained in this product are excreted in breast milk and may cause diarrhea in infants.

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.

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, or 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 Hepatic impairment, Jaundice (frequency unknown)

Liver disease 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, Redness, Pruritus, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, 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

750 g (2.5 g × 300 packets)

105 g (2.5 g × 42 packets)

24. REFERENCE REQUEST AND CONTACT INFORMATION

JPS Pharmaceutical CO., LTD

4-42-22 Higashiyamata, Tsuzukiku, Yokohama City, Kanagawa Prefecture 224-0023, Japan

TEL : 045-593-2060

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Manufactured and Distributed by:

JPS Pharmaceutical CO., LTD

196-1 Hagadai, Hagamachi, Hagagun, Tochigi Prefecture 321-3325, Japan