

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ04130000
Date of Initial Marketing in Japan	Nov. 1986

Kampo product

JPS Saikokeishito Extract Granules for Ethical Use

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Product Name	JPS Saikokeishito Extract Granules for Ethical Use	
Active Ingredients	JP Bupleurum Root	5.0 g
	JP Pinellia Tuber	4.0 g
	JP Cinnamon Bark	2.5 g
	JP Peony Root	2.0 g
	JP Scutellaria Root	2.0 g
	JP Ginseng	2.0 g
	JP Jujube	2.0 g
	JP Glycyrrhiza	1.5 g
	JP Ginger	1.0 g
	7.5 g/day of this product contains 3.8 g of a dried JP Saikokeishito extract of the abovemixed 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 sweet and bitter
ID Code	J-10

4. INDICATIONS

Symptoms include gastroenteritis mostly with abdominal pain, Common cold with mild fever, chills, headache, or nausea, Late-stage symptoms of cold

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 Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc. [See 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.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACK GROUNDS

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
Preparations containing Glycyrrhiza Shakuyakukanzoto Hochuekkito Yokukansan, etc.	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 tubule, an acceleration of decrease in the serum potassium level has been suggested.
Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/L-cysteine Monoammonium Glycyrrhizinate/Glycine/DL-methionine combination tablets, etc.		
[See 8.2, 11.1.2, 11.1.3]		

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 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 8.2, 10.2]

11.1.4 Hepatic impairment, jaundice (both 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, Redness, Pruritus, Urticaria, etc.
Gastrointestinal	Diarrhea, Constipation, Dyspepsia, etc.
Urinary	Pollakiuria, Painful micturition, Hematuria, Feeling of residual urine, Cystitis, etc.

15. OTHER PRECAUTIONS

15.1 Information Based on Clinical Use

Many cases of adverse reactions of interstitial pneumonia have been reported in concomitant use of shosaikoto, a similar prescription, with interferon- α .

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

500 g
750 g (2.5 g \times 300 packets)
105 g (2.5 g \times 42 packets)

24. REFERENCE REQUEST AND CONTACT

INFORMATION

JPS Pharmaceutical CO., LTD
4-42-22 Higashiyamata, Tsuzukiku, Yokohama City, Kanagawa Prefecture
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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