Revised: Dec. 2023（1st Version）

Storage：Store at room temperature
Shelf Life：3 years

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ04128000
Date of Initial Marketing in Japan	Nov. 1986

Kampo product

JPS Kamishoyosanryo Extract Granules for Ethical Use

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Product Name	JPS Kamishoyosanryo Extract Granules for Ethical Use	
Active Ingredients	JP Japanese Angelica Root	3.0 g
	JP Peony Root	3.0 g
	JP Atractylodes Lancea Rhizome	3.0 g
	JP Poria Sclerotium	3.0 g
	JP Bupleurum Root	3.0 g
	JP Moutan Bark	2.0 g
	JP Gardenia Fruit	2.0 g
	JP Glycyrrhiza	2.0 g
	JP Ginger	1.0 g
	JP Mentha Herb	1.0 g
	7.5 g/day of this product contains 3.8 g of a dried JP Kamishoyosan 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 yellow-brown
Smell	Characteristic smell
Taste	Slightly sweet and bitter
ID Code	J-24

4. INDICATIONS

The following symptoms of those women with delicate constitution who are easily fatigued and are apt to have stiffness shoulder, psychoneurotic symptoms including anxiety, and sometimes tendency to constipation: Oversensitivity to cold, delicate constitution, menstrual irregularity, dysmenorrhea, climacteric disturbance and automatic imbalance syndrome peculiar to women resembling climacteric disturbance

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, 11.1.1, 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 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.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACK GROUNDS

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 Brest-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. Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/L-cysteine Monoammonium Glycyrrhizinate/Glycine/DL-Methionine combination tablets, etc. [See 8.2, 11.1.1, 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 tubule, 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 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 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 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

500 g
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