Revised: Dec. 2023（1st Version）

Storage：Store at room temperature
Shelf Life：3 years

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ04766000
Date of Initial Marketing in Japan	Oct. 1987

Kampo product

JPS Tokishakuyakusanryo Extract Granules for Ethical Use

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Product Name	JPS Tokishakuyakusanryo Extract Granules for Ethical Use
Active Ingredients	JP Japanese Angelica Root 3.0 g JP Cnidium Rhizome 3.0 g JP Peony Root 4.0 g JP Poria Sclerotium 4.0 g JP Atractylodes Lancea Rhizome 4.0 g JP Alisma Tuber 4.0 g 7.5 g/day of this product contains 4.6 g of a dried JP Tokishakuyakusan 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 sweet and bitter
ID Code	J-23

4. INDICATIONS

The following symptoms in patients with relatively poor physical strength, with sensitivity to cold, tendency to anemia, fatigue, and sometimes complaint of lower abdominal pain, dull headaches, dizziness, shoulder muscle stiffness, tinnitus, palpitation, etc.:
Menstrual irregularity, menstrual abnormality, menstrual pain, climacteric disturbance, disorders before and after childbirth or miscarriage (anemia, fatigue, malaise, dizziness, swelling), dizziness, dull headache, shoulder muscle stiffness, low back pain, coldness in the legs, chilblains, swelling, and chloasma.

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.

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
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 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.

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.

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Pruritus, etc.
Liver	Hepatic function abnormal (increased AST, ALT, 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

750 g（2.5 g × 300 packets）
10 5g（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