Revised: Dec. 2023（1st Version）

Storage：Store at room temperature
Shelf Life：3 years

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ04763000
Date of Initial Marketing in Japan	Oct. 1987

Kampo product

JPS Orengedokuto Extract Granules for Ethical Use

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Product name	JPS Orengedokuto Extract Granules for Ethical Use
Active ingredients	JP Coptis Rhizome 1.5 g JP Phellodendron Bark 1.5 g JP Scutellaria Root 3.0 g JP Gardenia Fruit 2.0 g 7.5 g/day of this product contains 1.60 g of a dried JP Orengedokuto 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	Bitter
ID Code	J-15

4. INDICATIONS

The following symptoms in patients who have relatively good physical strength, have a tendency to have hot flushes and red face, and tend to be irritable:
Epistaxis, hypertension, Insomnia, neurotic disorder, gastritis, hangover, menopausal and female climacteric states, dizziness, palpitations, eczema/dermatitis, cutaneous pruritus

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 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 11.1.5]
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

9.1 Patients with Complication or History of diseases, etc.
9.1.1 Patients with extremely weakened constitution
Adverse reactions are likely to occur, and the 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.
11.1 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 Hepatic impairment, jaundice (frequency unknown)
Hepatic impairment and/or jaundice with marked elevations of AST, ALT, Al-P, γ-GTP, etc. may occur.Hepatic function failure and/or jaundice with marked elevations of AST, ALT, Al-P, γ-GTP, etc. may occur.
11.1.3 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 8.2]

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Urticaria, 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）
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