Revised: Dec. 2023（1st Version）

Storage：Store at room temperature
Shelf Life：3 years

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ04659000
Date of Initial Marketing in Japan	Oct. 1987

Kampo product

JPS San'oshashinto Extract Granules for Ethical Use

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Product Name	JPS San'oshashinto Extract Granules for Ethical Use
Active Ingredients	JP Rhubarb 1.0 g JP Scutellaria Root 1.0 g JP Coptis Rhizome 1.0 g 2.5 g/day of this product contains 0.7 g of a dried San'oshashinto 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 bitter
ID Code	J-113

4. INDICATIONS

The following symptoms in patients who have relatively good physical strength, have a tendency to have hot flushes, red face, mental anxiety, and tend to be constipated:
Concomitant symptoms of hypertension (hot flushes, shoulder muscle stiffness, tinnitus, dull headache, sleeplessness, anxiety), nosebleeds, hemorrhoidal bleeding, constipation, climacteric disturbance, menopausal and female climacteric states

6. DOSAGE AND ADMINISTRATION

The usual adult dose is 2.5 g/day orally in a dose 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, abdominal pain, diarrhea, etc. may occur.
9.1.3 Patients with extremely weakened constitution
Adverse reactions are likely to occur, and its 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 Brest-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, 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.
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.
11.2 Other Adverse Reactions

	Frequency unknown
Gastrointestinal	Anorexia, 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