

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ04770000
Date of Initial Marketing in Japan	Oct. 1987

## Kampo product

## JPS Shimbuto Extract Granules for Ethical Use

## 3. COMPOSITION AND PRODUCT DESCRIPTION

## 3.1 Composition

Product Name	JPS Shimbuto Extract Granules for Ethical Use	
Active Ingredients	JP Poria Sclerotium	5.0 g
	JP Peony Root	3.0 g
	JP Atractylodes Lancea Rhizome	3.0 g
	JP Ginger	1.0 g
	JP Powdered Processed Aconite Root	1.0 g
	7.5 g/day of this product contains 2.6 g of a dried JP Shimbuto 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 bitter
ID Code	J-30

## 4. INDICATIONS

The following symptoms in patients with decreased metabolism: Fever of various kinds, visceral ptosis, gastro-intestinal laxity, chronic enteritis, chronic nephritis, urticaria, eczema, cerebral hemorrhage, motor and sensory paralysis due to spinal cord disease

## 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. Special attention should be paid to concomitant use with preparations containing Processed Aconite Root

## 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACK GROUNDS

- 9.1 Patients with complication or history of diseases, etc.
- 9.1.1 Patients with good physical strength  
Adverse reactions are likely to occur, and its symptoms may be aggravated.
- 9.1.2 Patients who are sensitive to heat, have severe hot flushes, and a red face  
Palpitation, hot flushes, numbness of the tongue, nausea, etc. may occur.
- 9.5 Pregnant Women  
It is not recommended to administer this product to pregnant women or women who may possibly be pregnant. Adverse reactions of Powdered Processed Aconite Root contained in this product are likely to occur.
- 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  
This product should be administered with care. This product contains Powdered Processed Aconite Root.
- 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, Redness, Pruritus, Urticaria, etc.
Other	Palpitations, Hot flushes, Numbness of the tongue, Nausea, 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