

-Kampo product-

Powerful Drug
(500g Bottle only)

SG-07

OHSUGI Hachimijoganryo
Extract Granules G

SG-07 T

OHSUGI Hachimijoganryo
Extract T Tablets
(Hachimijogan)

Storage : Store at room temperature

Shelf Life : 3 years

	Approval No.	Date of Initial Marketing in Japan
Granules G	16100AMZ03901000	October 1986
T Tablets	16100AMZ04186000	October 1986

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	OHSUGI Hachimijoganryo Extract Granules G	OHSUGI Hachimijoganryo Extract T Tablets
Active ingredient	The daily dose of this product, 7.5 g, contains 4.6 g of the dried extract (Hachimijoganryo extract) from the following mixed crude drugs.	The daily dose of this product, 18 tablets, contains 4.6 g of the dried extract (Hachimijoganryo extract) from the following mixed crude drugs.
	JP Rehmannia Root	5 g
	JP Cornus Fruit	3 g
	JP Dioscorea Rhizome	3 g
	JP Alisma Tuber	3 g
	JP Poria Sclerotium	3 g
	JP Moutan Bark	3 g
	JP Cinnamon Bark	1 g
	JP Powdered Processed Aconite Root	1 g
	JP : Japanese Pharmacopoeia	
Excipients	Lactose Hydrate, Corn Starch and Magnesium Stearate	Microcrystalline Cellulose, Magnesium Aluminometasilicate, Carmellose Calcium, Magnesium Stearate, Hypromellose, Titanium Oxide, FD&C Yellow No.6 [Sunset Yellow FCF], FD&C Blue No.1 [Brilliant Blue FCF] and FD&C Red No.3 [Erythrosine]

3.2 Product Description

Brand name	OHSUGI Hachimijoganryo Extract Granules G	OHSUGI Hachimijoganryo Extract T Tablets
Dosage form	Granules	Film-coated tablets
Tone	Light grayish brown to light grayish and dark brown-colored granules	Light brown-colored film-coated tablets
Smells	Uniquely	-
Tastes	Slightly bitter and acidic	-
Form	-	Front
		Back
		Side
Diameter	-	About 9.0 mm
Thickness	-	About 5.4 mm
Weight	-	About 330 mg
ID Code	SG - 0 7	SG - 0 7 T

4. INDICATIONS

The following symptoms in patients who have easily fatigued, with cold limbs, have decreased urine output or polyuria, and sometimes dry mouth:

Leg pain, low back pain, numbness, blurred vision in the elderly, itching, dysuria, polyuria, swelling

6. DOSAGE AND ADMINISTRATION

< OHSUGI Hachimijoganryo Extract Granules G >

The usual adult dose is 7.5 g/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, body weight, and symptoms.

< OHSUGI Hachimijoganryo Extract T Tablets >

The usual adult dose is 18 tablets/day orally in 2 or 3 times before or between meals. The dosage may be adjusted according to the patient's age, 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.

SHO: The term "SHO" refers to a particular pathological status of a patient evaluated by the Kampo diagnosis, and is patterned according to the patient's constitution, symptoms, etc. Kampo products should be used after confirmation that it is suitable for the identified "SHO" of the patient.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

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 the symptoms may be aggravated.

9.1.2 Patients who are sensitive to heat, have severe hot flushes, and red face

Palpitation, hot flushes, numbness of the tongue, nausea, etc. may occur.

9.1.3 Patients with an extremely weak gastrointestinal tract

Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, constipation, etc. may occur.

9.1.4 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, and adverse reactions of Powdered Processed Aconite Root are likely to occur.

9.6 Breast-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, etc.
Liver	Hepatic function abnormal (increases in AST, ALT, T-Bil, etc.)
Gastrointestinal	Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, constipation, etc.
Other	Palpitation, hot flushes, numbness of the tongue, 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

< OHSUGI Hachimijigoganryo Extract Granules G >

500 g [Bottle]

735 g (2.5 g × 294 packets) [Sachet]

210 g (2.5 g × 84 packets) [Sachet]

< OHSUGI Hachimijigoganryo Extract T Tablets >

1,764 tablets (6 tablets × 294 packets) [Sachet]

504 tablets (6 tablets × 84 packets) [Sachet]

24. REFERENCE REQUEST AND CONTACT INFORMATION

Dep. of PMS Information,

Ohsumi Pharmaceutical Co., Ltd.

1-8-6, Yamasaka, Higashiumiyoshi-ku, Osaka 546-0035

06-6629-9058

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Marketing Authorization Holder

Ohsumi Pharmaceutical Co., Ltd.

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