

## -Kampo product-

SG-16

# OHSUGI Hangekobokuto

## Extract Granules G

SG-16 T

# OHSUGI Hangekobokuto

## Extract T Tablets

(Hangekobokuto)

Storage : Store at room temperature

Shelf Life : 3 years

	Approval No.	Date of Initial Marketing in Japan
Granules G	16100AMZ03877000	October 1986
T Tablets	16100AMZ04187000	October 1986

### 3. COMPOSITION AND PRODUCT DESCRIPTION

#### 3.1 Composition

Brand name	OHSUGI Hangekobokuto Extract Granules G	OHSUGI Hangekobokuto Extract T Tablets
Active ingredient	The daily dose of this product, 3.0 g, contains 1.4 g of the dried extract (Hangekobokuto extract) from the following mixed crude drugs.	The daily dose of this product, 12 tablets, contains 1.4 g of the dried extract (Hangekobokuto extract) from the following mixed crude drugs.
	JP Pinellia Tuber 6 g JP Poria Sclerotium 5 g JP Ginger 1 g JP Magnolia Bark 3 g JP Perilla Herb 2 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 Hangekobokuto Extract Granules G	OHSUGI Hangekobokuto Extract T Tablets
Dosage form	Granules	Film-coated tablets
Tone	Light grayish dark brown-colored granules	Light brown-colored film-coated tablets
Smells	Uniquely	-
Tastes	Hot initially and then slightly bitter	-
Form	-	Front
		Back
Diameter	-	About 9.0 mm
Thickness	-	About 5.4 mm
Weight	-	About 310 mg
ID Code	SG-16	SG-16 T

#### 4. INDICATIONS

The following symptoms in patients who have depressed feeling, feeling of a foreign body in the throat or esophagus, sometimes accompanied by palpitations, dizziness, nausea, etc.:

Anxiety neurosis, gastrointestinal neurosis, mild hyperemesis gravidarum, coughing, hoarseness

#### 6. DOSAGE AND ADMINISTRATION

< OHSUGI Hangekobokuto Extract Granules G >

The usual adult dose is 3.0 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 Hangekobokuto Extract T Tablets >

The usual adult dose is 12 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.

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

##### 9.5 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 Breast-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, redness, pruritus, etc.
Liver	Hepatic function abnormal (increased AST, ALT, 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 Hangekobokuto Extract Granules G >

500 g [Bottle]

294 g (1.0 g × 294 packets) [Sachet]

84 g (1.0 g × 84 packets) [Sachet]

< OHSUGI Hangekobokuto Extract T Tablets >

1,176 tablets (4 tablets × 294 packets) [Sachet]

336 tablets (4 tablets × 84 packets) [Sachet]

## 24. REFERENCE REQUEST AND CONTACT INFORMATION

Dep. of PMS Information,

Ohsugi Pharmaceutical Co., Ltd.

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

06-6629-9058

## 26. MARKETING AUTHORIZATION HOLDER, etc.

### 26.1 Marketing Authorization Holder

Ohsugi Pharmaceutical Co., Ltd.

1-1-2, Tennojichominami Abeno-ku, Osaka 545-0002