

Revised: Aug 2011 (5th version)

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| Standard Commodity Classification No. of Japan |
| 875200   |

- Kampo-preparation-

# TSUMURA Hangekobokuto Extract Granules for Ethical Use

<hangekobokuto>

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|---|
| <b>Storage</b>                                  |
| Store in light-resistant, air-tight containers. |

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|--|--------------|
| Approval No.                                   | (61AM)3263   |
| Date of listing in the NHI reimbursement price | October 1986 |
| Date of initial marketing in Japan             | October 1986 |

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| <b>Expiration date</b>   |
| Use before the expiration date indicated on the container and the outer package. |

## DESCRIPTION

|             |   |  |
|-------------|---|--|
| Composition | 7.5 g of TSUMURA Hangekobokuto extract granules contains 2.5 g of a dried extract of the following mixed crude drugs. |  |
|             |   | JP Pinellia Tuber ..... 6.0 g<br>JP Poria Sclerotium ..... 5.0 g<br>JP Magnolia Bark ..... 3.0 g<br>JP Perilla Herb ..... 2.0 g<br>JP Ginger ..... 1.0 g<br>(JP: The Japanese Pharmacopoeia) |
|             | Inactive ingredients  | JP Magnesium Stearate<br>JP Lactose Hydrate<br>Sucrose Esters of Fatty Acids   |
| Description | Dosage form   | Granules   |
|             | Color   | Grayish-brown  |
|             | Smell   | Characteristic smell   |
|             | Taste   | Sweet and pungent  |
|             | ID code   | TSUMURA/16   |

## INDICATIONS

Hangekobokuto is indicated for the relief of the following symptoms of those patients who have depressed feelings and a feeling of foreign body in the throat and oesophagus and who sometimes have palpitation, dizziness, nausea, etc.:

Anxiety neurosis, nervous gastritis, hyperemesis gravidarum, coughing, hoarseness, nervous oesophageal stricture, and insomnia

## 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.

## PRECAUTIONS

### 1. Important Precautions

- When this product is used, the patient's "SHO" (constitution/symptoms) should be taken into account. The patient's progress should be carefully monitored, and if no improvement in symptoms/findings is observed, continuous treatment should be avoided.
- When this product is coadministered with other Kampo-preparations (Japanese traditional herbal medicines), 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-preparations (Japanese traditional herbal medicines) should be used after confirmation that it is suitable for the identified "SHO" of the patient.

### 2. Adverse Reactions

This product has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

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|---|-------------------------------|
|   | <b>Incidence unknown</b>      |
| <b>Hypersensitivity</b><br><small>Note 1)</small> | Rash, Redness, Pruritus, etc. |

Note 1) If such symptoms are observed, administration should be discontinued.

### 3. Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

### 4. Use during Pregnancy, Delivery or Lactation

The safety of this product in pregnant women has not been established. Therefore, the product should be used in pregnant women, women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

**5. Pediatric Use**

The safety of this product in children has not been established. [Insufficient clinical data]

**PACKAGING**

Bottles of 500 g and boxes of 5 kg (500 g × 10 bottles)

2.5 g × 42 packets

2.5 g × 189 packets

**REQUEST FOR LITERATURE SHOULD BE MADE TO:**

Consumer Information Services Center

Tsumura & Co.

2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan

**Manufactured and Distributed by:**

Tsumura & Co.

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