

Revised: August 2017 (9th version)

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

- Kampo-preparation -

# TEIKOKU Byakkokaninjinto Extract Granules

&lt; Byakkokaninjinto &gt;

| Storage  |
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| Store at room temperature in a tight container. [See the "Precaution for handling" section.] |

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|--|-------------|
| Approval No.                                   | (61AM) 3746 |
| Date of listing in the NHI reimbursement price | July 1988   |
| Date of initial marketing in Japan             | July 1988   |
| Date of latest reevaluation                    | April 2014  |

| Expiration date  |
|--|
| Byakkokaninjinto should be used before the expiration date indicated on the label and the package. |

## DESCRIPTION

|             |   |  |
|-------------|---|--|
| Composition | 9.0 g of TEIKOKU Byakkokaninjinto Extract Granules contains 4.20 g of a dried water extract of the following mixed crude drugs.   |  |
|             | JP Anemarrhena Rhizome ----- 5.0 g<br>JP Gypsum ----- 15.0 g<br>JP Glycyrrhiza ----- 2.0 g<br>JP Brown Rice ----- 8.0 g<br>JP Ginseng ----- 3.0 g<br>(JP: The Japanese Pharmacopoeia) |  |
| Description | Inactive ingredients  | JP Lactose Hydrate<br>JP Microcrystalline Cellulose<br>JP Magnesium Stearate |
|             | Dosage form   | Granules   |
|             | Color   | Light brown  |
|             | Smell   | Characteristic smell   |
|             | Taste   | Sweet and bitter   |
|             | ID code   | TEIKOKU 34   |

## INDICATIONS

Thirst and hot flushes

## DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 3.0 g of TEIKOKU Byakkokaninjinto Extract Granules three times daily before meals.

The dosage may be adjusted according to the patient's age, body weight, and symptoms.

## PRECAUTIONS

### 1. Careful Administration (Byakkokaninjinto should be administered with care in the following patients.)

- (1) Patients with weak gastrointestinal tract [Oral cavity discomfort, anorexia, epigastric distress, soft feces, diarrhea, etc. may occur.]
- (2) Patients with greatly declined constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

## 2. Important Precautions

- (1) 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.
- (2) Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc., and if any abnormality is observed, administration should be discontinued.
- (3) 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.

## 3. Drug Interactions

### Precautions for coadministration (Byakkokaninjinto should be administered with care when coadministered with the following drugs.)

| Drugs   | Signs, Symptoms, and Treatment  | Mechanism and Risk Factors   |
|---|---|--|
| Preparations containing Glycyrrhiza                             | Pseudoaldosteronism is likely to occur.   | Since glycyrrhizinic acid has an accelerating action on the potassium excretion at the renal tubules, an acceleration of decrease in the serum potassium level has been suggested. |
| Preparations containing glycyrrhizinic acid or glycyrrhizinates | Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section "Clinically significant adverse reactions".) |  |

#### 4. 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.

##### (1) Clinically significant adverse reactions

**1) Pseudoaldosteronism:** Pseudoaldosteronism such as hypokalemia, increased blood pressure, retention of sodium/body fluid, edema, increased body weight, etc. may occur. The patient should be carefully monitored (measurement of serum potassium level, etc.), and if any abnormality is observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

**2) Myopathy:** Myopathy may occur as a result of hypokalemia. The patient should be carefully monitored, and if any abnormality such as weakness, convulsion/paralysis of limbs, etc. are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

##### (2) Other adverse reactions

|                                  | Incidence unknown   |
|----------------------------------|---|
| <b>Hypersensitivity</b><br>Note) | Rash, Pruritus, Urticaria, etc.   |
| <b>Hepatic</b>                   | Hepatic dysfunction [increased AST (GOT) and ALT (GPT) levels, etc.]              |
| <b>Gastrointestinal</b>          | Oral cavity discomfort, Anorexia, Epigastric distress, Soft feces, Diarrhea, etc. |

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

#### 5. Use in the Elderly

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

#### 6. 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.

#### 7. Pediatric Use

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

### PRECAUTIONS FOR HANDLING

1. This product should not be stored in direct rays and should be stored in a cool place with, if possible, little humidity.
2. Since it is hygroscopic property, this product should not be stored in humid places after opening.

### PACKAGING

- Bottles of 500 g
- Boxes of 3.0 g× 42 packets
- Boxes of 3.0 g×252 packets

### REQUEST FOR LITERATURE SHOULD BE MADE TO:

Product Information Unit,  
Pharmaceutical Sales & Marketing Dept.  
Teikoku Seiyaku Co., Ltd.  
6-6 Nihonbashi-kobunacho, Chuo-Ku, Tokyo  
103-0024, Japan  
Tel 0120-189-567

### Manufactured by:

Teikoku Kampo Seiyaku Co., Ltd.  
80-11 Kitahara, Donari, Donari-cho, Awa, Tokushima  
771-1506, Japan

### Distributed by:

Teikoku Seiyaku Co., Ltd.  
567, Sanbonmatsu, Higashikagawa, Kagawa  
769-2695, Japan