TSUMURA Shokenchuto Extract Granules for Ethical Use

**DESCRIPTION**

**Composition**

- 15.0 g of TSUMURA Shokenchuto extract granules contains 3.75 g of a dried extract of the following mixed crude drugs and 10.0 g of JP Koi.
  - JP Peony Root: 6.0 g
  - JP Cinnamon Bark: 4.0 g
  - JP Jujube: 4.0 g
  - JP Glycyrrhiza: 2.0 g
  - JP Ginger: 1.0 g

**Inactive ingredients**

- JP Magnesium Stearate
- JP Lactose Hydrate

**Description**

- Dosage form: Granules
- Color: Light grayish white
- Smell: Characteristic smell
- Taste: Sweet and slightly pungent

**ID code**: TSUMURA/99

**INDICATIONS**

Shokenchuto is indicated for the relief of the following symptoms accompanied by any of delicate constitution and easily fatigued, a poor complexion, abdominal pain, palpitation, hot flushes of the limbs, coldness, pollakiuria, or polyuria:

- Delicate constitution in childhood, fatigue and malaise, nervousness, chronic gastroenteritis, nocturnal enuresis in children, and night cry

**DOSAGE AND ADMINISTRATION**

The usual adult dose is 15.0 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**

   (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.

2. **Drug Interactions**

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

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Signs, Symptoms, and Treatment</th>
<th>Mechanism and Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Preparations containing Glycyrrhiza</td>
<td>Pseudoadosteronism is likely to occur. Besides, myopathy is likely to occur as a result of hypokalemia. (Refer to the section “Clinically significant adverse reactions.”)</td>
<td>Since glycyrrhizic 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.</td>
</tr>
<tr>
<td>(2) Preparations containing glycyrrhizic acid or glycyrrhizates</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Storage**

Store in light-resistant, air-tight containers.

**Expiration date**

Use before the expiration date indicated on the container and the outer package.

**Approval No.**

(61AM)1152

**Date of listing in the NHI reimbursement price**

October 1986

**Date of initial marketing in Japan**

October 1986
3. **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

<table>
<thead>
<tr>
<th>Hypersensitivity Note 1</th>
<th>Incidence unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rash, Redness, Pruritus, etc.</td>
<td></td>
</tr>
</tbody>
</table>

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

4. **Use in the Elderly**

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

5. **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.

6. **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 × 84 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 102-8422, Japan

**Manufactured and Distributed by:**

   Tsumura & Co.

   2-17-11 Akasaka, Minato-ku, Tokyo 102-8422, Japan