Revised: June 2009 (5th version)

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

- Kampo-preparation-

# TSUMURA Tsudosan Extract Granules for Ethical Use

<tsudosan>

| Storage |
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| Store in light-resistant, air-tight containers. |

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

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| Approval No. | (61AM)1145 |
| Date of listing in the NHI reimbursement price | October 1986 |
| Date of initial marketing in Japan | October 1986 |

## DESCRIPTION

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|---|---|---|
| Composition | 7.5 g of TSUMURA Tsudosan extract granules contains 4.5 g of a dried extract of the following mixed crude drugs.<br>JP Immature Orange ..... 3.0 g<br>JP Rhubarb ..... 3.0 g<br>JP Japanese Angelica Root ..... 3.0 g<br>JP Glycyrrhiza …… 2.0 g<br>JP Safflower ……..... 2.0 g<br>JP Magnolia Bark ……... 2.0 g<br>JP Sappan Wood …… 2.0 g<br>JP Citrus Unshiu Peel …… 2.0 g<br>JP Akebia Stem …….. 2.0 g<br>Anhydrous Mirabilitum …….. 1.8 g<br>(JP: The Japanese Pharmacopoeia) | |
| | Inactive ingredients | JP Magnesium Stearate<br>JP Lactose Hydrate |
| Description | Dosage form | Granules |
| | Color | Yellow-brown |
| | Smell | Characteristic smell |
| | Taste | Acrid and bitter |
| | ID code | TSUMURA/105 |

## INDICATIONS

Tsudosan is indicated for the relief of the following symptoms of those patients with a comparatively strong constitution who have tenderness in the lower abdomen and are likely to have constipation:

Menstrual irregularity, menalgia, climacteric disturbance, low back pain, constipation, bruise (contusion), and symptoms associated with hypertension (headache, dizziness, and shoulder stiffness)

## 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. Careful Administration (Tsudosan should be administered with care in the following patients.)**

(1) Patients with diarrhea or soft feces [These symptoms may be aggravated.]

(2) Patients with an extremely weak gastrointestinal tract [Anorexia, Epigastric distress, Nausea, abdominal pain, diarrhea, etc. may occur.]

(3) Patients with anorexia, nausea or vomiting [These symptoms may be aggravated.]

(4) 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. Special caution should be exercised when this product is coadministered with preparations containing Rhubarb.

(4) Since there is an individual difference in the cathartic action of Rhubarb, caution should be exercised concerning the dosage and administration.

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 (Tsudosan should be administered with care when coadministered with the following drugs.)**

| Drugs | Signs, Symptoms, and Treatment | Mechanism and Risk Factors |
|---|---|---|
| (1) Preparations containing Glycyrrhiza<br>(2) Preparations containing glycyrrhizinic acid or glycyrrhizinates | Pseudoaldosteronism is likely to occur. Besides, myopathy is likely to occur as a result of hypokalemia.<br>(Refer to the section "Clinically significant adverse reactions".) | 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. |

**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 |
|---|---|
| **Hepatic** | Hepatic dysfunction [increased AST (GOT) and ALT (GPT) levels, etc.] |
| **Gastrointestinal** | Anorexia, Epigastric distress, Nausia, Abdominal pain, Diarrhea, etc. |

**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**

(1) Use of this product in pregnant women, women who may possibly be pregnant is not recommended. [Rhubarb (uterotonic action and congestive action on the intrapelvic organs), anhydrous Mirabilitum (uterotonic action), Safflower contained in this product may cause premature birth or abortion.]

(2) This product should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in this product may be excreted in breast milk and induce diarrhea in nursing infants.]

**7. Pediatric Use**

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

**8. Other Precautions**

This product contains anhydrous Mirabilitum. Caution should be exercised when continuous treatment with this product is given to patients who need limited salt-intake therapeutically.

## 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:**

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