**TSUMURA Mashiningan Extract Granules for Ethical Use**  
**<mashiningan>**

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- **2. Important Precautions**
  - (1) When TJ-126 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) When TJ-126 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 TJ-126 is coadministered with preparations containing Rhubarb.
  - (3) 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. Adverse Reactions**
  - TJ-126 has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.
- **4. Use in the Elderly**
  - Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.
- **Expiration date**
- **Storage**

### DESCRIPTION

<table>
<thead>
<tr>
<th>Composition</th>
<th>Dosage form</th>
<th>Inactive ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.5 g of TSUMURA Mashiningan extract granules contains 2.25 g of a dried extract of the following mixed crude drugs.</td>
<td>Granules</td>
<td>JP Magnesium Stearate, JP Lactose Hydrate</td>
</tr>
<tr>
<td>JP Hemp Fruit …………………........</td>
<td>5.0 g</td>
<td></td>
</tr>
<tr>
<td>JP Rhubarb …………………........</td>
<td>4.0 g</td>
<td></td>
</tr>
<tr>
<td>JP Immature Orange …………………</td>
<td>2.0 g</td>
<td></td>
</tr>
<tr>
<td>JP Apricot Kernel …………………</td>
<td>2.0 g</td>
<td></td>
</tr>
<tr>
<td>JP Magnolia Bark …………………</td>
<td>2.0 g</td>
<td></td>
</tr>
<tr>
<td>JP Peony Root …………………</td>
<td>2.0 g</td>
<td></td>
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</tbody>
</table>

**Inactive ingredients**

- JP Magnesium Stearate
- JP Lactose Hydrate

<table>
<thead>
<tr>
<th>Description</th>
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<tbody>
<tr>
<td>Color</td>
</tr>
<tr>
<td>Smell</td>
</tr>
<tr>
<td>Taste</td>
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<td>ID code</td>
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### INDICATIONS

TSUMURA Mashiningan Extract Granules (hereafter TJ-126) is indicated for the relief of the following symptoms: Constipation

### 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 (TJ-126 should be administered with care in the following patients.)
   - (1) Patients with diarrhea, soft feces [These symptoms may be aggravated.]
   - (2) Patients with an extremely weak gastrointestinal tract [Anorexia, abdominal pain, diarrhea, etc. may occur.]

2. Important Precautions
   - (1) When TJ-126 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) When TJ-126 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 TJ-126 is coadministered with preparations containing Rhubarb.
   - (3) 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. Adverse Reactions

TJ-126 has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

### 4. Use in the Elderly

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

#### Incidence unknown

<table>
<thead>
<tr>
<th>Incidence unknown</th>
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<tbody>
<tr>
<td>Gastrointestinal</td>
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</table>
5. Use during Pregnancy, Delivery or Lactation

(1) Use of TJ-126 in pregnant women, women who may possibly be pregnant is not recommended. [The uterotonic action and congestive action on the intrapelvic organs of Rhubarb contained in this product may cause premature birth or abortion.]

(2) TJ-126 should be administered with care in nursing mothers. [Anthraquinone derivatives in Rhubarb contained in TJ-126 may be excreted in breast milk and induce diarrhea in nursing infants.]

6. Pediatric Use

The safety of TJ-126 in children has not been established.

[Insufficient clinical data]

PACKAGING

Bottles of 500 g
2.5 g × 42 packets
2.5 g × 189 packets

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Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan

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