Revised: March 2013 (6th version)

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

- Kampo-preparation-

# TSUMURA Daibofuto Extract Granules for Ethical Use

<daibofuto>

| 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. | (62AM)694 |
| Date of listing in the NHI reimbursement price | October 1987 |
| Date of initial marketing in Japan | October 1987 |

## DESCRIPTION

| | | |
|---|---|---|
| Composition | 10.5 g of TSUMURA Daibofuto extract granules contains 8.00 g of a dried extract of the following mixed crude drugs.<br>JP Astragalus Root ..... 3.0 g<br>JP Rehmannia Root ……..... 3.0 g<br>JP Peony Root ..... 3.0 g<br>JP Atractylodes Lancea Rhizome ..... 3.0 g<br>JP Japanese Angelica Root …… 3.0 g<br>JP Eucommia Bark …… 3.0 g<br>JP Saposhnikovia Root …….. 3.0 g<br>JP Cnidium Rhizome ……. 2.0 g<br>JP Glycyrrhiza ..... 1.5 g<br>JP Notopterygium ……..…….. 1.5 g<br>JP Achyranthes Root …….. 1.5 g<br>JP Jujube …… 1.5 g<br>JP Ginseng ……. 1.5 g<br>JP Processed Ginger ..... 1.0 g<br>JP Powdered Processed Aconite Root ... 1.0 g<br>(JP: The Japanese Pharmacopoeia) | |
| | Inactive ingredients | JP Magnesium Stearate<br>JP Lactose Hydrate |
| Description | Dosage form | Granules |
| | Color | Dark Gray |
| | Smell | Characteristic smell |
| | Taste | Slightly acid and bitter |
| | ID code | TSUMURA/97 |

## INDICATIONS

TSUMURA Daibofuto Extract Granules (hereafter TJ-97) is indicated for the relief of the following symptoms of those patients who have swollen, painful, paralyzed, and stiff joints that are hard to bend or stretch:

Articular rheumatism of the lower limbs, chronic arthritis, and gout

## DOSAGE AND ADMINISTRATION

The usual adult dose is 10.5 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-97 should be administered with care in the following patients.)**

(1) Patients with strong constitution [Adverse reactions are likely to occur, and the symptoms may be aggravated.]

(2) Patients with sensitivity to heat, a tendency towards hot flush and red face. [Palpitation, hot flush, numbness of the tongue, nausea, etc. may occur.]

(3) Patients with an extremely weak gastrointestinal tract [Anorexia, epigastric distress, nausea, vomiting, diarrhea, etc. may occur.]

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

**2. Important Precautions**

(1) When TJ-97 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 TJ-97 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 TJ-97 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-97 is coadministered with preparations containing Aconite Root.

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 (TJ-97 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**

TJ-97 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 |
|---|---|
| **Hypersensitivity** Note 1) | Rash, Uriticaria, etc. |
| **Gastrointestinal** | Anorexia, Epigastric distress, Nausea, Vomiting, Diarrhea, etc. |
| **Others** | Palpitation, Hot flush, Numbness of the tongue, etc. |

Note 1) 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**

Use of TJ-97 in pregnant women, women who may possibly be pregnant is not recommended. [Achyranthes Root contained in TJ-97 may cause premature birth or abortion. Besides, adverse reactions due to Powdered Processed Aconite Root contained in TJ-97 are likely to occur.]

**7. Pediatric Use**

TJ-97 should be administered with care in children. [T TJ-97 contains Powdered processed aconite root.]

**8. Other Precautions**

Eczema, dermatitis, etc. may be aggravated.

## PHARMACOLOGY

**Effects on a rheumatoid arthritis model**

TJ-97, which was administered by gastric gavage for 12 weeks, reduced the severity of type II collagen-induced arthritis and the serum anti-collagen antibody levels in mice. Histologically, it suppressed cartilage and bone erosion.

## PACKAGING

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

## REFERENCES

1) Wang, L. R. et al. Am. J. Chin. Med. 1999, **27**(2), p.205.

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

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