■ 17 ■

Kampo-preparation-

TSUMURA Goreisan Extract Granules for Ethical Use

<table>
<thead>
<tr>
<th>Storage</th>
<th>Approval No.</th>
<th>(61AM)3287</th>
</tr>
</thead>
<tbody>
<tr>
<td>Store in light-resistant, air-tight containers.</td>
<td>Date of listing in the NHI reimbursement price</td>
<td>October 1986</td>
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<tr>
<td></td>
<td>Date of initial marketing in Japan</td>
<td>October 1986</td>
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</table>

<table>
<thead>
<tr>
<th>Expiration date</th>
<th>Description</th>
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<tbody>
<tr>
<td>Use before the expiration date indicated on the container and the outer package.</td>
<td>Dosage form Granules</td>
</tr>
<tr>
<td></td>
<td>Color Light grayish-brown</td>
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<tr>
<td></td>
<td>Smell Characteristic smell</td>
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<tr>
<td></td>
<td>Taste Slightly pungent</td>
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<td></td>
<td>ID code TSUMURA/17</td>
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DESCRIPTION

Composition
7.5 g of TSUMURA Goreisan extract granules (hereafter TJ-17) contains 2.0 g of a dried extract of the following mixed crude drugs.

- JP Alisma Rhizome ............................................. 4.0 g
- JP Atractylodes Lancea Rhizome ......................... 3.0 g
- JP Polyporus Sclerotium .................................... 3.0 g
- JP Poria Sclerotium ........................................... 3.0 g
- JP Cinnamon Bark ............................................. 1.5 g

(JP: The Japanese Pharmacopoeia)

Inactive ingredients
- JP Magnesium Stearate
- JP Lactose Hydrate

INDICATIONS

TJ-17 is indicated for the relief of the following symptoms of those patients with oral dryness and decreased urine volume:
- Edema, nephrosis, alcoholic hangover, acute gastrointestinal catarrh, diarrhea, nausea, vomiting, dizziness, water retention in the stomach, headache, uremia, heat-stroke, and diabetes mellitus

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. Important Precautions

   (1) When TJ-17 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-17 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. Adverse Reactions

   TJ-17 has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

   Hypersensitivity
   Note 1: Rash, Redness, Pruritus, etc.

   Hepatic
   Abnormality of hepatic function [Increased AST (GOT), ALT (GPT), and γ-GTP etc.]

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

3. Use in the Elderly

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

4. Use during Pregnancy, Delivery or Lactation

   The safety of TJ-17 in pregnant women has not been established. Therefore, TJ-17 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.

5. Pediatric Use

   The safety of TJ-17 in children has not been established. [Insufficient clinical data.]
PHARMACOLOGY

1. Antidiarrheic effect
   Oral administration of Goreisan to mice inhibited the diarrhea induced by magnesium sulfate\(^1\).

2. Hydragogue effect
   Oral administration of Goreisan to mice increased the urine volume in water intoxication mice but not in water deprivation mouse\(^2\).

3. Actions on dry mouth
   Oral administration of Goreisan to diabetic xerostomia mouse models inhibited the decrease in the salivation rate\(^3\).

4. Action mechanism
   Goreisan shows pharmacological effects via the following actions.
   (1) Diuretic action
       Goreisan inhibited the Na\(^+\) channel in cells derived from the cortical collecting tubule (MDCK cells) in the distal tubule derived from the dog kidneys \((\text{in vitro})\) \(^4\).
   (2) Increasing effect on urine volume
       Oral administration of Goreisan to rats downregulated aquaporin (AQP)3 mRNA in renal cortex as well as AQP2 mRNA and AQP3 mRNA in renal medulla, subsequently increased the urine volume\(^5\).

PACKAGING
   Bottles of 500 g and boxes of 5 kg (500 g \(\times\) 10 bottles)
   2.5 g \(\times\) 42 packets
   2.5 g \(\times\) 189 packets

REFERENCES

REQUEST FOR LITERATURE SHOULD BE MADE TO:
Consumer Information Services Center
Tsumura & Co.
2-17-11 Akasaka, Minato-ku, Tokyo 107-8521, Japan
TEL:0120-329970 FAX:03-5574-6610

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