Revised: August 2017 (10th version)

Standard Commodity Classification No. of Japan
875200

- Kampo-preparation -

TEIKOKU Hachimigan Extract Granules

< Hachimigan >

Powerful drug: Bottles of 500 g

Storage
Store at room temperature in a tight container. [See the “Precaution for handling” section.]

Expiration date
Hachimigan should be used before the expiration date indicated on the label and the package.

Approval No.	(62AM) 0060
Date of listing in the NHI reimbursement price	July 1988
Date of initial marketing in Japan	July 1988

DESCRIPTION

Composition	9.0 g of TEIKOKU Hachimigan Extract Granules contains 4.60 g of a dried water extract of the following mixed crude drugs. JP Rehmannia Root ---------- 5.0 g JP Cornus Fruit ---------- 3.0 g JP Dioscorea Rhizome ---------- 3.0 g JP Alisma Tuber ---------- 3.0 g JP Poria Sclerotium ---------- 3.0 g JP Moutan Bark ---------- 3.0 g JP Cinnamon Bark ---------- 1.0 g JP Powdered Processed Aconite Root ---- 1.0 g (JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	JP Lactose Hydrate JP Microcrystalline Cellulose JP Magnesium Stearate
Description	Dosage form	Granules
	Color	Grayish brown to dark grayish brown
	Smell	Characteristic smell
	Taste	Bitter
	ID code	TEIKOKU 7

INDICATIONS

The following symptoms of those patients with decreased urine volume or polyuria sometimes having dry mouth who are easily fatigued and easily feel cold in the extremities:
Leg pain, low back pain, numbness, blurred vision in old patients, pruritus, dysuria, frequent urination, and edema

DOSAGE AND ADMINISTRATION

For oral use, the usual adult dosage is 3.0 g of TEIKOKU Hachimigan Extract Granules three times daily before or between meals.
The dosage may be adjusted according to the patient’s age, body weight, and symptoms.

PRECAUTIONS

1. Careful Administration (Hachimigan 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, feeling of enlarged abdomen, diarrhea, constipation, etc. may occur.]
(4) Patients with anorexia, nausea or vomiting [These 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) 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 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. 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.

	Incidence unknown
Hypersensitivity Note)	Rash, Redness, Pruritus, etc.
Hepatic	Abnormality of hepatic function [Increased AST (GOT), ALT (GPT) and total bilirubin, etc. levels]
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, Constipation, etc.
Others	Palpitation, Hot flush, Numbness of the tongue, etc.

Note) 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

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

6. Pediatric Use

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

PRECAUTIONS FOR HANDLING

1.This product should not be stored in direct rays and should be stored in a cool place with, if possible, little humidity.
2.Since it is hygroscopic property, this product should not be stored in humid places after opening.

PACKAGING

Bottles of 500 g
Boxes of 3.0 g× 42 packets
Boxes of 3.0 g×252 packets

REQUEST FOR LITERATURE SHOULD BE MADE TO:

Product Information Unit,
Pharmaceutical Sales & Marketing Dept.
Teikoku Seiyaku Co., Ltd.
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