

Storage: Store at room temperature

Shelf Life:3 years

Kampo product

N7

Powerful drug

Approval No.	16100AMZ03832000
Date of Initial Marketing in Japan	October 1986

Kotaro Hachimiganryo Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Hachimiganryo Extract Fine Granules
Active ingredient	9.0g of Kotaro Hachimiganryo Extract Fine Granules contains 5.3g of the dried extract of the following mixed crude drugs.
	JP Rehmannia Root.....5.0g
	JP Cornus Fruit3.0g
	JP Dioscorea Rhizome3.0g
	JP Alisma Tuber3.0g
	JP Poria Sclerotium.....3.0g
	JP Moutan Bark3.0g
	JP Cinnamon Bark1.0g
	JP Powdered Processed Aconite Root 2.....1.0g (JP: Japanese Pharmacopoeia)
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

3.2 Product Description

Dosage form	Fine granules
Color	Dark brown to deep brown
Taste	Slightly hot and sweet
Odor	Characteristic odor
ID code	N7

4. INDICATIONS

In patients with the conditions below, symptoms include marked fatigue and malaise and are prone to cold limbs, but sometimes have hot flushes, low back pain and a dry throat, frequent urination, decreased urine output, feeling of residual urine due to a decreased urine output, or conversely, increased urine output, especially nocturnal polyuria.

Dry mouth due to increased blood glucose, diabetes mellitus, arteriosclerosis, chronic nephritis, nephrosis, contracted kidney, bladder catarrh, edema, impotence, sciatica, postpartum beriberi, climacteric disturbance, senile eczema, hypotension.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 9.0g daily in 2 or 3 divided doses before or between meals.

The dosage may be adjusted according to the patient's age, body weight, and symptoms.

8. IMPORTANT PRECAUTIONS

8.1 When this product is used, the patient's "SHO"

(constitution/symptoms) should be taken into consideration. The patient's progress should be carefully monitored, and if no improvement in symptoms or findings is observed, continuous administration should be avoided.

8.2 When this product is used in combination with other Kampo products, etc., attention should be paid to the duplication of the contained crude drugs. Special attention should be paid to concomitant use with preparations containing Processed Aconite Root.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with good physical strength

Adverse reactions are likely to occur, and the symptoms may be aggravated.

9.1.2 Patients who are sensitive to heat, have severe hot flushes, and red face

Palpitation, hot flushes, numbness of the tongue, nausea, etc. may occur.

9.1.3 Patients with an extremely weak gastrointestinal tract

Anorexia, epigastric distress, nausea, vomiting, abdominal pain, diarrhea, constipation, etc. may occur.

9.1.4 Patients with anorexia, nausea, or vomiting

These symptoms may be aggravated.

9.5 Pregnant Women

It is not recommended to administer this product to pregnant women or women who may possibly be pregnant. Moutan Bark contained in this product may cause premature birth or miscarriage, and adverse reactions of Powdered Processed Aconite Root are likely to occur.

9.6 Breast-feeding Women

Considering the therapeutic benefits and the benefits of breastfeeding, continuation or discontinuation of breastfeeding should be considered.

9.7 Pediatric Use

This product should be administered with care. This product contains Powdered Processed Aconite Root.

9.8 Geriatric Use

Since the physiological functions are generally decrease in elderly patients, careful supervision is recommended; measures such as reducing the dose may be considered.

11. ADVERSE REACTIONS

The following adverse reactions may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, Pruritus, etc.
Liver	Hepatic function abnormal (increases in AST, ALT, T-Bil, etc.)
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea Constipation, etc.
Other	Palpitation, Hot flushes, Numbness of the tongue, etc.

20. PRECAUTIONS FOR HANDLING

20.1 To maintain the quality of the product, avoid moisture as much as possible and store in a cool place, away from direct sunlight.

20.2 Avoid moisture, especially after opening, and handle with care.

20.3 Since this product is made from crude drugs, the color of the product may vary.

22. PACKAGING

500g [bottle, loose]

3.0g×42 packets [sachets]

3.0g×168 packets [sachets]

24. REFERENCE REQUEST AND CONTACT
INFORMATION

Pharmaceutical Division, Kotaro Pharmaceutical Co., Ltd.
5-23, Nakatsu 2-chome, Kita-ku, Osaka 531-0071, Japan

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Marketing Authorization Holder

Kotaro Pharmaceutical Co., Ltd.
5-23, Nakatsu 2-chome, Kita-ku, Osaka 531-0071, Japan