

Shorage: Store at room temperature

Shelf Life:3 years

Kampo product

N314

Kotaro Shishihakuhto Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

| | |
|-------------------|---|
| Brand name | Kotaro Shishihakuhto Extract Fine Granules |
| Active ingredient | 6.0g of Kotaro Shishihakuhto Extract Fine Granules contains 1.2g of the dried extract of the following mixed crude drugs. |
| | JP Gardenia Fruit..... 3.0g |
| | JP Glycyrrhiza..... 1.0g |
| | JP Phellodendron Bark..... 2.0g (JP: Japanese Pharmacopoeia) |
| Excipients | Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate |

3.2 Product Description

| | |
|-------------|---------------------------|
| Dosage form | Fine granules |
| Color | Yellowish brown to yellow |
| Taste | Slightly bitter |
| Odor | Characteristic odor |
| ID code | N314 |

4. INDICATIONS

The following symptoms in patients who feel pressure in the liver:
Jaundice, cutaneous pruritus, hangover.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6.0g 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 Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc. [See Sections 10.2, 11.1.1, 11.1.2]

8.3 Prolonged administration of preparations containing Gardenia Fruit (for more than 5 years in most cases) may cause mesenteric phlebosclerosis with pigmentation, edema, erosion, ulceration, and stenosis of the colon. In the case of long-term administration, periodic examinations such as CT and colonoscopy are recommended. [See Section 11.1.3]

8.4 When this product is used in combination with other Kampo products, etc., attention should be paid to the duplication of the contained crude drugs.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.5 Pregnant Women

This product should be used in pregnant women or women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

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

No clinical studies have been conducted in children.

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.

10. INTERACTIONS

10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.)

| Drugs | Signs, Symptoms, and Treatment | Mechanism and Risk Factors |
|---|---|--|
| Glycyrrhiza-containing preparations Shakuyakukanzoto Hochuekkito Yokukansan, etc. Preparations containing glycyrrhizic acid and its salts Monoammonium Glycyrrhizinate/Glycine/L-cysteine Monoammonium Glycyrrhizinate/Glycine/DL-Methionine combination tablets, etc. [See Sections 8.2, 11.1.1, 11.1.2] | Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur. | Since glycyrrhizic acid has an accelerating effect on potassium excretion in the renal tubules, an acceleration of decrease in the serum potassium level has been suggested. |

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.

11.1 Clinically Significant Adverse Reactions

11.1.1 Pseudoaldosteronism (frequency unknown)

Pseudoaldosteronism such as hypokalaemia, blood pressure increased, retention of sodium/body fluid, edema, and body weight gain may occur. Patients should be carefully monitored (e.g., measurement of serum potassium levels), and if any abnormalities are observed, administration should be discontinued, and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

11.1.2 Myopathy (frequency unknown)

Myopathy may occur as a result of hypokalaemia. Patients should be carefully monitored, and if any abnormalities such as feelings of weakness, muscle cramp in extremities, or paralysis are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]

11.1.3 Mesenteric phlebosclerosis (frequency unknown)

Mesenteric phlebosclerosis may occur with long-term administration of this product. If abdominal pain, diarrhea, constipation, abdominal distension, etc. are repeatedly observed, or if fecal occult blood test is positive, administration should be discontinued, and examinations such as CT and colonoscopy should be performed, and appropriate measures should be taken. Intestinal resection has been reported in some cases. [See Section 8.3]

11.2 Other Adverse Reactions

| | Frequency unknown |
|------------------|---|
| Gastrointestinal | Anorexia, Epigastric distress, Diarrhea, 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]
- 2.0g×42 packets[sachets]
- 2.0g×231 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