Revised: January 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Storage: Store at room temperature
Shelf Life:3 years

Approval No.	16200AMZ00056000
Date of Initial Marketing in Japan	October 1987

Kampo product

NC127

Powerful drug

Kotaro Maobushisaishinto Extract Capsules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Maobushisaishinto Extract Capsules
Active ingredient	6 capsules of Kotaro Maobushisaishinto Extract Capsules contains 1200mg of the dried extract of the following mixed crude drugs. JP Ephedra Herb……4.0g JP Asiasarum Root……3.0g JP Powdered Processed Aconite Root 2……1.0g (JP: Japanese Pharmacopoeia)
Excipients	Carmellose Calcium, Light Anhydrous Silicic Acid, Microcrystalline Cellulose, Synthetic aluminum Silicate, Magnesium Stearate, Corn Starch, Hydroxypropyl Starch, Magnesium Aluminometasilicate Capsule Materials: Blue No.1 [Brilliant Blue FCF], Yellow No.5 [Sunset Yellow FCF], Titanium Oxide, Gelatin, Sodium Lauryl Sulfate

3.2 Product Description

Dosage form	Hard Capsules
Color	Cap: Orange, opaque Body: Beige, opaque Contents: Yellowish brown powder
Taste	Contents: Bitter
Odor	Contents: Characteristic odor
Appearance	
Size	No.2
ID code	NC127

4. INDICATIONS

The following symptoms in patients with the conditions below: general malaise, lethargy, mild fever, or chills.
Common cold, bronchitis.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6 capsules(1.68g) 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 a red face
Palpitation, hot flushes, numbness of the tongue, nausea, etc. may occur.

9.1.3 Patients with an extremely weak gastrointestinal tract
Dry mouth, anorexia, epigastric distress, nausea, vomiting, etc. may occur.

9.1.4 Patients with anorexia, nausea, or vomiting
These symptoms may be aggravated.

9.1.5 Patients with a significant sweating tendency
Excessive sweating, systemic weakness, etc. may occur.

9.1.6 Patients with cardiovascular disorders, including angina pectoris or myocardial infarction, or patients with a history of such disorders
The disease and its symptoms may be aggravated.

9.1.7 Patients with severe hypertension
The disease and its symptoms may be aggravated.

9.1.8 Patients with urination impaired
The disease and its symptoms may be aggravated.

9.1.9 Patients with hyperthyroidism
The disease and its symptoms may be aggravated.

9.2 Patients with renal impairment

9.2.1 Patients with severe renal disorder
The disease and the symptoms may be aggravated.

9.5 Pregnant Women
It is not recommended to administer this product to pregnant women or women who may be pregnant. Adverse reactions of Powdered Processed Aconite Root contained in this product 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.

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
Ephedra Herb-containing preparations Kakkonto Shoseiryuto Maoto, etc. Ephedrine-containing preparations Ephedrine Hydrochloride dl-Methyl Ephedrine Hydrochloride Fexofenadine Hydrochloride/Pseudoephedrine Hydrochloride, etc. Monoamine Oxidase (MAO) inhibitors Selegiline Hydrochloride Rasagiline Mesilate, etc. Thyroid gland preparations Thyroxine Liothyronine, etc. Catecholamine preparations Adrenaline Isoprenaline, etc. Xanthine preparations Theophylline Diprophylline, etc.	Since insomnia, excessive sweating, tachycardia, palpitation, systemic weakness, mental excitement, etc. are likely to occur, this product should be administered with care by reducing the dosage, etc.	The sympathetic stimulation may be enhanced.

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 Hepatic impairment, jaundice (frequency unknown)

Hepatic impairment and/or jaundice with marked elevations of AST, ALT, Al-P, γ-GTP, etc. may occur.

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, etc.
Autonomic	Insomnia, Excessive sweating, Tachycardia, Palpitations, Systemic weakness, Mental excitement, etc.
Gastrointestinal	Dry mouth, Anorexia, Epigastric distress, Nausea, Vomiting, etc.
Urinary	Urination impaired, etc.
Other	Hot flushes, Numbness of the tongue, etc.

14. PRECAUTIONS CONCERNING USE

14.1 Precautions Concerning the Dispensing of the Drug

For the products that are dispensed in a PTP (press-through package) sheet, instruct the patient to remove the drug from the PTP sheet prior to use. If the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, resulting in severe complications such as mediastinitis.

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.

22. PACKAGING

100capsules(10capsules×10)[PTP]

300capsules(10capsules×30)[PTP]

600capsules(10capsules×60)[PTP]

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