

Storage: Store at room temperature

Shelf Life: 3 years

Kampo product

NC5

Approval No.	16100AMZ04022000
Date of Initial Marketing in Japan	October 1986


## Kotaro Anchusan Extract Capsules

### 3. COMPOSITION AND PRODUCT DESCRIPTION

#### 3.1 Composition

Brand name	Kotaro Anchusan Extract Capsules
Active ingredient	6 capsules of Kotaro Anchusan Extract Capsules contains 1500mg of the dried extract of the following mixed crude drugs.
	JP Cinnamon Bark ..... 4.0g
	JP Corydalis Tuber ..... 3.0g
	JP Oyster Shell..... 3.0g
	JP Fennel..... 1.5g
	JP Amomum Seed ..... 1.0g
	JP Glycyrrhiza..... 1.0g
	JP Alpinia Officinarum Rhizome..... 0.5g (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], Red No.3 [Erythrosine], Titanium Oxide, Gelatin, Sodium Lauryl Sulfate

#### 3.2 Product Description

Dosage form	Hard Capsules
Color	Cap: Blue, opaque Body: Beige, opaque Contents: Light yellow powder
Taste	Contents: Slightly sweet
Odor	Contents: Characteristic odor
Appearance	
Size	No.1
ID code	NC5

### 4. INDICATIONS

The following symptoms in patients with a thin body habitus and who have a tendency to have relaxed abdominal muscles, with stomach or abdominal pain, sometimes accompanied by heartburn, belching, anorexia, or nausea:

Neurotic gastritis, chronic gastritis, and gastric atony.

### 6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6 capsules(2.04g) 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 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]

#### 11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, Ruritus, 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

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.

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