

Storage: Store at room temperature

Shelf Life:3 years

Kampo product

Approval No.	16100AMZ03950000
Date of Initial Marketing in Japan	October 1986

N319

Kotaro Daisaikotokyodaio Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Daisaikotokyodaio Extract Fine Granules
Active ingredient	9.0g of Kotaro Daisaikotokyodaio Extract Fine Granules contains 5.7g of the dried extract of the following mixed crude drugs. JP Bupleurum Root.....6.0g JP Pinellia Tuber.....4.0g JP Ginger.....1.0g JP Scutellaria Root.....3.0g JP Peony Root.....3.0g JP Jujube.....3.0g JP Imature Orange.....2.0g (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 yellowish brown
Taste	Bitter
Odor	Characteristic odor
ID code	N319

4. INDICATIONS

The following symptoms in patients whose solar plexus is stiff and tight, with pain or pressure in the chest, flank or liver, which may also be accompanied by tinnitus, shoulder muscle stiffness, fatigue, anorexia, etc., but without constipation:

Hypertension, arteriosclerosis, gastrointestinal disease, bronchial asthma, jaundice, cholelithiasis, cholecystitis, insomnia, neurasthenia, impotence, pleurisy, hemorrhoids, hemiplegia.

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.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with extremely weakened constitution

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

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.

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