Revised: July 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Storage: Store at room temperature
Shelf Life: 3 years

Approval No.	16100AMZ03833000
Date of Initial Marketing in Japan	October 1986

Kampo product

N16

Kotaro Hangekobokuto Extract Fine Granules

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kotaro Hangekobokuto Extract Fine Granules
Active ingredient	6.0g of Kotaro Hangekobokuto Extract Fine Granules contains 2.2g of the dried extract of the following mixed crude drugs. JP Pinellia Tuber……6.0g JP Poria Sclerotium……5.0g JP Ginseng……1.0g JP Magnolia Bark ……3.0g JP Perilla Herb……2.0g (JP: Japanese Pharmacopoeia)
Excipients	Magnesium Stearate, Corn Starch, Lactose Hydrate, Pullulan, Magnesium Aluminometasilicate

3.2 Product Description

Dosage form	Fine granules
Color	Brown to grayish brown
Taste	Slightly bitter
Odor	Characteristic odor
ID code	N16

4. INDICATIONS

The following symptoms in patients with the conditions below: mental anxiety, a feeling of blockage from the throat to the chest, a feeling of stagnant bloating in the stomach, or usually with poor digestive function, sometimes accompanied by nausea and vomiting.
Bronchitis, hoarseness, coughing spell, bronchial asthma, neurogenic esophageal stenosis, weak stomach, cardiac asthma, neurotic disorder, neurasthenia, phobias, insomnia, mild hyperemesis gravidarum, other emesis, climacteric neurosis, edema, nervous headaches.

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 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.

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 (increased AST, ALT, 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