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Since this translation is prepared in July 2025 based on the Japanese text current at that time, the translation may not reflect the latest information, due to continuous revision of package inserts.

The latest Japanese text is available on PMDA website.

Kracie

Oct 2023 (1st version)

| | |
|--|------------------|
| Standard Commodity Classification No. of Japan | |
| 875200 | |
| Approval No. | 21900AMX00638000 |
| Date of Initial Marketing in Japan | Oct 1986 |

Kampo product

Kracie Orengedokuto Extract Tablets

Storage : Store at room temperature
Shelf Life : 3 years

EKT-15




3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

| | | | |
|----------------------|--|-------|--|
| Brand name | Kracie Orengedokuto Extract Tablets | | |
| Active ingredients | The daily dose of this product (18 tablets) contains 1,600 mg of JP Orengedokuto extract, derived from a mixture of the following crude drugs. | | |
| | JP Coptis Rhizome | 1.5 g | |
| | JP Phellodendron Bark | 1.5 g | |
| | JP Scutellaria Root | 3.0 g | |
| | JP Gardenia Fruit | 2.0 g | |
| Inactive ingredients | JP Magnesium Stearate, | | |
| | JP Carmellose Calcium, | | |
| | JP Light Anhydrous Silicic Acid, | | |
| | JP Lactose Hydrate, | | |
| | JP Microcrystalline Cellulose | | |

(JP: The Japanese Pharmacopoeia)

3.2 Product Description

| | | | |
|-------------|---|---|---|
| Dosage form | Uncoated tablet | | |
| Color | Brown to yellow-brown | | |
| Odor | Practically none or slightly characteristic odor | | |
| Taste | Bitter | | |
| Appearance | Surface | Back | Side |
| |  |  |  |
| Diameter | 9.2 mm | | |
| Thickness | 4.6 mm | | |
| Mass | 330 mg | | |
| ID code | EKT-15 | | |

4. INDICATIONS

The following symptoms in patients who have relatively good physical strength, have a tendency to have hot flushes and red face, and tend to be irritable:

Epistaxis, hypertension, insomnia, neurotic disorder, gastritis, hangover, menopausal and female climacteric states, dizziness, palpitations, eczema/dermatitis, cutaneous pruritus

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 18 tablets daily in two or three 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 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]

8.3 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

9.1 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 decreased 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.

11.1 Clinically Significant Adverse Reactions

11.1.1 Interstitial pneumonia (frequency unknown)

If cough, dyspnea, pyrexia, abnormal lung sound, etc. are observed, administration of this product should be discontinued, and examinations such as chest X-ray and chest CT scan should be performed immediately, and appropriate measures such as administration of corticosteroid should be taken. In addition, patients should be advised to discontinue administration of this product and contact the physician immediately if cough, dyspnea, or pyrexia, etc. occur.

11.1.2 Hepatic impairment, jaundice (frequency unknown)

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

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 8.2]

11.2 Other Adverse Reactions

| | |
|------------------|---|
| | Frequency unknown |
| Hypersensitivity | Rash, Urticaria, etc. |
| Gastrointestinal | Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, 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

252 tablets (3 tablets × 6 packets × 14 sheets) [sachets]

1,764 tablets (3 tablets × 6 packets × 98 sheets) [sachets]

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Manufactured and Distributed by:

OMINEDO PHARMACEUTICAL INDUSTRY CO., LTD.

574, Nenarigaki, Yamatotakada-city, Nara 635-0051, Japan

26.2 Distributed by:

Kracie Pharmaceutical, Ltd.

20-20, Kaigan 3-Chome, Minato-ku, Tokyo 108-8080, Japan