

Disclaimer

This English translation is prepared by Marketing Authorization Holder.

The Japanese language package insert is the official document, and this translation is provided solely as a reference material. In the case of any discrepancy between the two versions, the original Japanese version prevails.

The provider of this translation shall not be responsible for any damage that may be attributed to the use of the translation.

This translation shall not be reproduced, reprinted or used for profit.

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.	21900AMX00633000
Date of Initial Marketing in Japan	Dec 1987

Kampo product

Kracie Kamikihito Extract Tablets

Storage : Store at room temperature
Shelf Life : 3 years

EKT-49




3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Kamikihito Extract Tablets
Active ingredients	The daily dose of this product (27 tablets) contains 6,000 mg of JP Kamikihito extract, derived from a mixture of the following crude drugs.
	JP Ginseng 3.0 g
	JP Atractylodes Rhizome 3.0 g
	JP Poria Sclerotium 3.0 g
	JP Astragalus Root 2.0 g
	JP Japanese Angelica Root 2.0 g
	JP Polygala Root 1.5 g
	JP Bupleurum Root 3.0 g
	JP Gardenia Fruit 2.0 g
	JP Glycyrrhiza 1.0 g
	JP Saussurea Root 1.0 g
	JP Jujube 1.5 g
	JP Ginger 0.5 g
	JP Jujube Seed 3.0 g
	JP Longan Aril 3.0 g
Inactive ingredients	JP Magnesium Stearate,
	JP Carmellose Calcium,
	JP Light Anhydrous Silicic Acid,
	JP Microcrystalline Cellulose

(JP: The Japanese Pharmacopoeia)

3.2 Product Description

Dosage form	Uncoated tablet		
Color	Light brown to brown		
Odor	Practically none or slightly characteristic odor		
Taste	Slightly bitter, pungent afterwards		
Appearance	Surface	Back	Side
			
Diameter	9.2 mm		
Thickness	4.9 mm		
Mass	330 mg		
ID code	EKT-49		

4. INDICATIONS

The following symptoms in patients with weak constitution and poor complexion:

Anemia, insomnia, anxiety disorder, neurotic disorder

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 27 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 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 Prolonged administration of preparations containing Gardenia Fruit (for more than 5 years in most cases) may cause mesenteric phleboscrosis 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]

8.4 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 anorexia, nausea, or vomiting

These 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.

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]

11.1.3 Mesenteric phleboscrosis (frequency unknown)

Mesenteric phleboscrosis 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 8.3.]

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Abdominal pain, Diarrhea, etc.

12. INFLUENCE ON LABORATORY TESTS

Administration of this product may cause an increase in blood AG (1,5-anhydro-D-glucitol).

15. OTHER PRECAUTIONS

15.1 Information Based on Clinical Use

Eczema or dermatitis may be aggravated.

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

378 tablets (3 tablets × 6 packets × 21 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