Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Approval No.	16100AMZ03516000
Date of Initial Marketing in Japan	Oct 1986

Kampo product

Kracie Shosaikoto Extract Fine Granules

Storage : Store at room temperature
Shelf Life : 3 years

KB-9 EK-9

1. WARNING

1.1 This product may cause interstitial pneumonia, which may lead to serious outcomes such as death if appropriate treatment is not applied early. Monitor the patient's condition closely, and discontinue administration of this product immediately if cough, dyspnea, pyrexia, abnormal lung sound, abnormal chest X-ray, abnormal chest CT, etc. are observed [See Sections 2.2, 2.3, 8.4, 9.3.1-9.3.3, 11.1.1].

1.2 Instruct patients to discontinue use of this product and contact the medical personnel immediately if cough, dyspnea, or pyrexia occurs [See Section 11.1.1].

2. CONTRAINDICATIONS (This product is contra-indicated to the following patients.)

2.1 Patients receiving interferon preparations [See Sections 10.1 and 11.1.1]

2.2 Patients with cirrhosis or liver cancer [See Sections 1.1, 9.3.1-9.3.3, 11.1.1]

2.3 Patients with hepatic impairment in chronic hepatitis with a platelet count ≤ 100,000/mm^3 [See Sections 1.1, 8.4, 9.3.1-9.3.3, 11.1.1]

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	Kracie Shosaikoto Extract Fine Granules
Active ingredients	The daily dose of this product (6.0 g) contains 5,400 mg of JP Shosaikoto extract, derived from a mixture of the following crude drugs. JP Bupleurum Root 7.0 g JP Pinellia Tuber 5.0 g JP Scutellaria Root 3.0 g JP Jujube 3.0 g JP Ginseng 3.0 g JP Glycyrrhiza 2.0 g JP Ginger 1.0 g
Inactive ingredients	JP Magnesium Stearate, JP Light Anhydrous Silicic Acid, JP Microcrystalline Cellulose, Hydrated Silicon Dioxide

(JP: The Japanese Pharmacopoeia)

3.2 Product Description

Dosage form	Fine granules
Color	Light yellow-brown to yellow-brown
Odor	Characteristic odor
Taste	Slightly sweet and bitter
ID code	KB-9 (3.0 g per sachet) EK-9 (2.0 g per sachet)

4. INDICATIONS

1. The following symptoms in patients with moderate physical strength, distress in the upper abdomen, coated tongue, oral discomfort, anorexia, and sometimes mild pyrexia and nausea: acute febrile diseases of various kinds, pneumonitis, bronchitis, bronchial asthma, common cold, lymphadenitis, chronic gastrointestinal disorders, and complicated postpartum recovery

2. Improvement of hepatic impairment in chronic hepatitis

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 6.0 g 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

[Common indications]

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, 11.1.2, 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.

[Improvement of hepatic impairment in chronic hepatitis]

8.4 During treatment with this product, attention should be paid to changes in the platelet count, and if a decreased platelet count is observed, administration should be discontinued. [See Sections 1.1, 2.3, 9.3.1-9.3.3, 11.1.1]

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.

9.3 Patients with Hepatic Impairment

9.3.1 Patients with cirrhosis or liver cancer

The product should not be administered. Interstitial pneumonia may occur, resulting in serious outcomes such as death. [See Sections 1.1, 2.2, 2.3, 8.4, 11.1.1.]

9.3.2 Patients with hepatic impairment in chronic hepatitis with a platelet count of ≤ 100,000/mm^3

The product should not be administered. Cirrhosis is suspected. [See Sections 1.1, 2.2, 2.3, 8.4,11.1.1.]

9.3.3 Patients with hepatic impairment in chronic hepatitis with a platelet count greater than 100,000/mm^3 and less than or equal to 150,000/mm^3

This product should be administered with care. The patient may have cirrhosis. [See sections 1.1, 2.2, 2.3, 8.4, 11.1.1]

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 Bresat-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
10.1 Contraindications for Co-administration (Do not co-administer with the following.)

Drugs	Signs, Symptoms, and Treatment	Mechanism and Risk Factors
Interferon preparations Interferon-α (Sumiferon, etc.) Interferon -β (Feron, etc.) [See Sections 2.1, 11.1.1]	Interstitial pneumonia may occur.	Mechanism unknown

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. Loop diuretics Azosemide Torasemide Furosemide, etc. Thiazide diuretics Trichlormethiazide Hydrochlorothiazide Benzylhydrochlorothiazide, etc. [See Sections 8.2, 11.1.2, 11.1.3]	Pseudoaldosteronism is likely to occur. As a result of hypokalaemia, myopathy is likely to occur.	Since glycyrrhizic acid and diuretics promote potassium excretion in renal tubules, it is considered that a decrease in the serum potassium level may be promoted.

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.[See Sections 1.1, 1.2, 2.1-2.3, 8.4, 9.3.1-9.3.3, 10.1]
11.1.2 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]
11.1.3 Myopathy, rhabdomyolysis (frequency unknown)
Since myopathy and rhabdomyolysis may occur as a result of hypokalaemia, patients should be carefully monitored, if feelings of weakness, muscle weakness, myalgia, limb muscle cramp/paralysis, increased CK, or rise of myoglobin in blood or urine are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken. [See Sections 8.2, 10.2]
11.1.4 Hepatic impairment, jaundice (frequency unknown)
Hepatic impairment and/or jaundice with marked elevations of AST, ALT, Al-P, γ-GTP, etc. may occur.
11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Pruritus, Urticaria, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, Abdominal pain, Diarrhea, Constipation, etc.
Urinary	Pollakiuria, Painful micturition, Hematuria, Feeling of residual urine, Cystitis, 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
(KB-9)
3.0 g × 28 packets [sachets]
3.0 g × 168 packets [sachets]
(EK-9)
2.0 g × 42 packets [sachets]
2.0 g × 294 packets [sachets]
500 g [bottle]

26. MARKETING AUTHORIZATION HOLDER, etc.
26.1 Manufactured and Distributed by:
Kracie, Ltd.
20-20, Kaigan 3-Chome, Minato-ku, Tokyo 108-8080, Japan
26.2 Distributed by:
Kracie Pharmaceutical, Ltd.
20-20, Kaigan 3-Chome, Minato-ku, Tokyo 108-8080, Japan