Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan	
875200	
Approval No.	16100AMZ03607000
Date of Initial Marketing in Japan	Nov 1986

Powerful drug

Storage : Store at room temperature
Shelf Life : 3 years

Kampo product

SANWA Keishakuchimoto Extract Fine Granules

EK-180

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	SANWA Keishakuchimoto Extract Fine Granules
Active ingredients	The daily dose of this product (9.0 g) contains 5,100 mg of Keishakuchimoto extract, derived from a mixture of the following crude drugs. JP Cinnamon Bark 3.0 g JP Anemarrhena Rhizome 3.0 g JP Glehnia Root and Rhizome 3.0 g JP Ginger 1.0 g JP Peony Root 3.0 g JP Ephedra Herb 3.0 g JP Atractylodes Rhizome 4.0 g JP Glycyrrhiza 1.5 g JP Processed Aconite Root 1.0 g
Inactive ingredients	JP Lactose Hydrate, JP Corn Starch, JP Microcrystalline Cellulose, JP Light Anhydrous Silicic Acid, Partly Pregelatinized Starch

(JP: The Japanese Pharmacopoeia)

3.2 Product Description

Dosage form	Fine granules
Color	Brown
Odor	Characteristic odor
Taste	Bitter, sweet and a little pungent
ID code	EK-180

4. INDICATIONS

The following symptoms in patients with the conditions below: arthralgia, weight loss, swollen legs, dizziness and nausea.

Neuralgia, rheumatoid arthritis

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 9.0 g daily in three divided doses before or between meals.

The dosage may be adjusted according to the patient's age, 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 When this product is used in combination with other Kampo products, etc., attention should be paid to the duplication of the contained crude drugs. Special attention should be paid to concomitant use with preparations containing Processed Aconite Root.

9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS

9.1 Patients with Complication or History of Diseases, etc.

9.1.1 Patients with good physical strength

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

9.1.2 Patients who are sensitive to heat, have severe hot flushes, and red face

Palpitation, hot flushes, numbness of the tongue, nausea, etc. may occur.

9.1.3 Patients with an extremely weak gastrointestinal tract

Anorexia, epigastric distress, nausea, vomiting, etc. may occur.

9.1.4 Patients with anorexia, nausea, or vomiting

These symptoms may be aggravated.

9.1.5 Patients with a significant sweating tendency

Excessive sweating, systemic weakness, etc. may occur.

9.1.6 Patients with cardiovascular disorders, including angina pectoris or myocardial infarction, or patients with a history of such disorders

The disease and its symptoms may be aggravated.

9.1.7 Patients with severe hypertension

The disease and its symptoms may be aggravated.

9.1.8 Patients with urination impaired

The disease and its symptoms may be aggravated.

9.1.9 Patients with hyperthyroidism

The disease and its symptoms may be aggravated.

9.2 Patients with Renal Impairment

9.2.1 Patients with severe renal disorder

The disease and its symptoms may be aggravated.

9.5 Pregnant Women

It is not recommended to administer this product to pregnant women or women who may possibly be pregnant. Adverse reactions of Processed Aconite Root contained in this product are likely to occur.

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

This product should be administered with care. This product contains Processed Aconite Root.

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
Ephedra Herb-containing preparations Kakkonto Shoseiryuto Maoto, etc. Ephedrine-containing preparations Ephedrine Hydrochloride dl-Methyl Ephedrine Hydrochloride Fexofenadine Hydrochloride/Pseudoephedrine Hydrochloride, etc. Monoamine Oxidase (MAO) inhibitors Selegiline Hydrochloride Rasagiline Mesilate, etc. Thyroid gland preparations Thyroxine Liothyronine, etc. Catecholamine preparations Adrenaline Isoprenaline, etc. Xanthine preparations Theophylline Diprophylline, etc.	Since insomnia, excessive sweating, tachycardia, palpitation, systemic weakness, mental excitement, etc. are likely to occur, this product should be administered with care by reducing the dosage, etc.	The sympathomimetic effect may be enhanced.
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]

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, Pruritus, etc.
Autonomic	Insomnia, Excessive sweating, Tachycardia, Palpitations, Systemic weakness, Mental excitement, etc.
Gastrointestinal	Anorexia, Epigastric distress, Nausea, Vomiting, etc.
Urinary	Urination impaired, etc.
Other	Hot flushes, Numbness of the tongue, 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

3.0 g × 42 packets [sachets]
3.0 g × 294 packets [sachets]
500 g [bottle]

26. MARKETING AUTHORIZATION HOLDER, etc.

26.1 Marketing Authorization Holder:

SANWA Shoyaku Co., Ltd.
6-1, Hiraide-Kogyo-Danchi, Utsunomiya-city, Tochigi , 321-0905, Japan

26.2 Distributed by:

Kracie Pharmaceutical,Ltd.
20-20, Kaigan 3-Chome, Minato-ku, Tokyo 108-8080, Japan