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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.	16100AMZ03615000
Date of Initial Marketing in Japan	Nov 1986

Kampo product

Powerful drug

SANWA Maobushisaishinto Extract Fine Granules

Storage : Store at room temperature
Shelf Life : 3 years

EK-127

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	SANWA Maobushisaishinto Extract Fine Granules		
Active ingredients	The daily dose of this product (4.5 g) contains 1,500 mg of Maobushisaishinto extract, derived from a mixture of the following crude drugs.		
	JP Ephedra Herb	4.0 g	
	JP Asiasarum Root	3.0 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 and slightly numbing
ID code	EK-127

4. INDICATIONS

The following symptoms in patients with the conditions below: chills, mild fever, general malaise, hypotension, headache, dizziness, pain and coldness in the limbs. Common cold, bronchitis, cough.

6. DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 4.5 g daily in 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 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

Dry mouth, 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.

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 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, Redness, etc.
Autonomic	Insomnia, Excessive sweating, Tachycardia, Palpitation, Systemic weakness, Mental excitement, etc.
Gastrointestinal	Dry mouth, 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

- 1.5 g \times 42 packets [sachets]
- 1.5 g \times 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.

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