Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Approval No.	16100AMZ03620000
Date of Initial Marketing in Japan	Nov 1986

Powerful drug

Storage : Store at room temperature
Shelf Life : 3 years

Kampo product

SANWA Shimbuto Extract Fine Granules

EK-30

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	SANWA Shimbuto Extract Fine Granules
Active ingredients	The daily dose of this product (4.5 g) contains 2,400 mg of JP Shimbuto extract, derived from a mixture of the following crude drugs. JP Poria Sclerotium 5.0 g JP Peony Root 3.0 g JP Ginger 1.0 g JP Atractylodes Rhizome 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
ID code	EK-30

4. INDICATIONS

The following symptoms in patients with the conditions below: cold limbs and lumbar region, marked fatigue and malaise, decreased urine output, a tendency toward diarrhea, palpitations and dizziness due to a decline in metabolic function.
Gastrointestinal weakness, chronic gastrointestinal catarrh, chronic nephritis.

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.

9.5 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.

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.

11.2 Other Adverse Reactions

	Frequency unknown
Hypersensitivity	Rash, Redness, Pruritus, Urticaria, etc.
Other	Palpitations, Hot flushes, Numbness of the tongue, Nausea, 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 × 42 packets [sachets]
1.5 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