Kracie

Oct 2023 (1st version)

Standard Commodity Classification No. of Japan
875200

Approval No.	16100AMZ03614000
Date of Initial Marketing in Japan	Nov 1986

Powerful drug

Storage : Store at room temperature
Shelf Life : 3 years

Kampo product

SANWA Bushirichuto Extract Fine Granules

EK-410

2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)

2.1 Patients with aldosteronism [The disease and its symptoms may be aggravated.]
2.2 Patients with myopathy [The disease and its symptoms may be aggravated.]
2.3 Patients with hypokalaemia [The disease and its symptoms may be aggravated.]

3. COMPOSITION AND PRODUCT DESCRIPTION

3.1 Composition

Brand name	SANWA Bushirichuto Extract Fine Granules
Active ingredients	The daily dose of this product (4.5 g) contains 2,800 mg of Bushirichuto extract, derived from a mixture of the following crude drugs. JP Ginseng 3.0 g JP Glycyrrhiza 3.0 g JP Atractylodes Rhizome 3.0 g JP Processed Ginger 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	Pungent and slightly sweet
ID code	EK-410

4. INDICATIONS

The following symptoms in patients with the conditions below: gastrointestinal weakness, pale complexion, lifeless face, heavy urine output, cold hands and feet, a tendency toward diarrhea, and frequent nausea, dizziness, dull headache, and stomach pain.
Chronic gastrointestinal catarrh, gastric atony

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, 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.

9.5 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
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, 11.1.1, 11.1.2]	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 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, 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