DESCRIPTION

1. Composition
Each daily dose (7.5 g) of this product contains 6,400 mg of hochuekkito extract powder extracted from the mixture of the following crude drugs.

Ginseng (JP) ---------------------------- 4.0 g
Atractyloides Rhizome (JP)----------- 4.0 g
Astragalus Root (JP) ------------------- 4.0 g
Japanese Angelica Root (JP)---------- 3.0 g
Jujube (JP)------------------------------- 2.0 g
Bupleurum Root (JP) ------------------ 2.0 g
Glycyrrhiza (JP) ------------------------ 1.5 g
Ginger (JP) ------------------------------ 0.5 g
Cimicifuga Rhizome (JP) ------------- 1.0 g
Citrus Unshiu Peel (JP)---------------- 2.0 g

(JP : The Japanese Pharmacopia)

It also contains magnesium stearate, microcrystalline cellulose, light anhydrous silicic acid, lactose and hydrated silicon dioxide as inactive ingredients.

2. Product description

DOSAGE AND ADMINISTRATION

The usual adult dosage for oral use is 7.5 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.

PRECAUTIONS

1. Important Precautions
(1) When this product is used, the patient’s “SHO” (constitution/symptoms) should be taken into account.
The patient’s progress should be carefully monitored, and if no improvement in symptoms/findings is observed, continuous treatment should be avoided.

The term “SHO” refers to a particular pathological status of a patient evaluated by the Kampo diagnosis, and is patterned according to the patient’s constitution, symptoms, etc.

Kampo-preparations (Japanese traditional herbal medicines) should be used after confirmation that it is suitable for the identified “SHO” of the patient.

(2) Since this product contains Glycyrrhiza, careful attention should be paid to the serum potassium level, blood pressure, etc., and if any abnormality is observed, administration should be discontinued.

(3) When this product is coadministered with other Kampo-preparations (Japanese traditional herbal medicines), etc., attention should be paid to the duplication of the contained crude drugs.

2. Drug Interactions
(1) Precautions for coadministration (Hochuekkito should be administered with care when coadministered with the following drugs.)
3. Adverse Reactions

This product has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

(1) Clinically significant adverse reactions

1) Interstitial pneumonia:
   If fever, cough, dyspnea, abnormal pulmonary sound (fine crepitation), etc. are observed, administration of this product should be discontinued, and examinations such as X-ray should be performed immediately and appropriate measures such as administration of adrenocortical hormones taken. Besides, the patient should be advised to discontinue this product immediately and to make contact with the physician in the event of fever, cough, dyspnea, etc.

2) Pseudoaldosteronism:
   Pseudoaldosteronism such as hypokalemia, increased blood pressure, retention of sodium/body fluid, edema, increased body weight, etc. may occur. The patient should be carefully monitored (measurement of serum potassium level, etc.), and if any abnormality is observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

3) Myopathy:
   Myopathy may occur as a result of hypokalemia. The patient should be carefully monitored, and if any abnormality such as weakness, convulsion/paralysis of limbs, etc. are observed, administration should be discontinued and appropriate measures such as administration of potassium preparations should be taken.

4) Hepatic dysfunction and jaundice:
   Hepatic dysfunction and/or jaundice with elevation of AST (GOT), ALT (GPT), Al-P and γ-GTP or other symptoms may occur. The patient should be carefully monitored for abnormal findings. Administration should be discontinued and appropriate therapeutic measures should be taken, if abnormalities are observed.

(2) Other adverse reactions

<table>
<thead>
<tr>
<th>Incidence unknown</th>
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<tbody>
<tr>
<td>Hypersensitivity¹</td>
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<tr>
<td>Gastrointestinal</td>
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</table>

Note

¹) If such symptoms are observed, administration should be discontinued.

4. Use in the Elderly

Because elderly patients often have reduced physiological function, careful supervision and measures such as reducing the dose are recommended.

5. Use during Pregnancy, Delivery or Lactation

The safety of this product in pregnant women has not been established. Therefore, the product should be used in pregnant women, women who may possibly be pregnant only if the expected therapeutic benefits outweigh the possible risks associated with treatment.

6. Pediatric Use

The safety of this product in children has not been established. [insufficient clinical data.]

7. Other precautions

Eczema, dermatitis, etc. may be aggravated.

PHARMACOLOGY

1. Suppression of leukopenia and acceleration of the recovery

The extract powder of this drug (orally administered) suppressed the decrease in the leukocyte numbers in the peripheral blood in mice treated with cyclophosphamide (CY) or exposed to radiation (γ-ray), and also accelerated the recovery of the numbers to the normal level. It is considered that the extract powder of this drug stimulated proliferation of the bone marrow multipotential stem cells and induced their differentiation to granulocytes or monocytes series to cause the recovery of the leukocyte numbers.

2. Production of active oxygen in neutrophils

The extract powder of this drug (orally administered) increased the production of active oxygen in neutrophils in normal or CY-treated mice.

3. Protective effect against infection

The extract powder of this drug (orally or subcutaneously administered) enhanced the protective effect against a systemic and respiratory infection by Pseudomonas aeruginosa in CY-treated mice.
PACKAGING
Kracie Hochuekkito Extract Fine Granules
1. KB-41   3.75 g × 28 packets
          3.75 g × 168 packets
2. EK-41   2.5 g × 42 packets
          2.5 g × 294 packets
          Bottles of 500g

REFERENCES

REQUEST FOR LITERATURE SHOULD BE MADE TO:
Drugs Information Services Center
Kracie Pharmaceutical, Ltd.
20-20, Kaigan 3-chome, Minato-ku, Tokyo 108-8080, Japan

Distributed by:
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