### Drug Information Sheet("Kusuri-no-Shiori")

Internal Revised: 10/2009

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

#### **Brand name:**Kracie Shoseiryuto Extract Tablets

Active ingredient: Shoseiryuto

Dosage form: light brown to brown tablet, diameter: 9.2mm, thickness: 4.7mm

Imprint or print on wrapping:EKT-19クラシエ小青竜湯(ショウセイリュウトウ)エキス錠3

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#### Effects of this medicine

This Kampo (Japanese traditional herbal) medicine has been prescribed according to your symptoms and constitution. This medicine has been prescribed to those patients with watery sputum, watery nasal discharge, nasal congestion, sneezing, stridor, coughing, lacrimation in the following diseases.

It is usually used to treat bronchitis, bronchial asthma, rhinitis, allergic rhinitis, allergic conjunctivitis, and common cold.

## The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.

- · If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
- If you have aldosteronism, hypokalemia or myopathy.
- If you have or have a history of cardiac disorders such as angina pectoris and myocardial infarction.
- · If you have hyperthyroidism.
- •If you have severe hypertension.
- · If you are pregnant or breastfeeding.
- •If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

#### Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((
- to be written by a healthcare professional))
- •In general, for adults, take . Strictly follow the instructions.
- •If you miss a dose, take 18 tablets a day orally in 2 or 3 divided doses before or between meals. The dosage may be adjusted according to your age, body weight and symptoms. You should not take two doses at one time.
- ·If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop taking this medicine unless your doctor instructs you to do so.

#### Precautions while taking this medicine

#### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, redness, itching, insomnia, excessive sweating, tachycardia, palpitations, excitation, loss of appetite, gastric distress, nausea, vomiting, abdominal pain, diarrhea, and urination disorder. If any of these symptoms occur, consult with your doctor or pharmacist.

# The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- •fever, dry cough, shortness of breath, difficulty breathing [interstitial pneumonia]
- ·decreased urine output, edema of face and limbs, heavy feeling in the eyelids, hand stiffness [pseudoaldosteronism]
- ·body dullness, weakness, cramp and numbness of limbs [myopathy]
- ·body dullness, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

#### Storage conditions and other information

- •Keep out of the reach of children. Store away from direct sunlight, heat and moisture.
- ·Discard the remainder. Do not store them.

#### For healthcare professional use only

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For further information, talk to your doctor or pharmacist.