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

Internal Revised: 04/2014

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 Orengedokuto Extract Tablets

Active ingredient: Orengedokuto

**Dosage form:**brown to yellow- brown tablet, diameter:9.2mm, thickness:4.6mm

Imprint or print on wrapping:EKT-15 クラシエ黄連解毒湯(オウレンゲドクトウ)エキス錠

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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 comparatively strong constitution who have a slight feeling of rush of blood to the head and have facial hot flushes, and a tendency to irritability.

It is usually used to treat nose bleeding, hypertension, insomnia, nervous breakdown, gastritis, alcoholic hangover, symptom of the menopausal state, dizziness, palpitation, eczema or dermatitis and cutaneous pruritus.

## 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 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 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. Strictly follow the instructions.
- •If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue with your regular dosing schedule. You should never 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, hives, loss of appetite, gastric discomfort, nausea, vomiting, abdominal pain and diarrhea. 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]
- •body dullness, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- •recurring abdominal pain, constipation, diarrhea, abdominal bloating [mesenteric phlebosclerosis]

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.