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

Internal Revised: 11/2014

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: CLARITIN Tablets 10mg**

Active ingredient:Loratadine

**Dosage form:**white tablet, diameter: 6.5 mm, thickness: 2.6 mm

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#### Effects of this medicine

This medicine relieves the symptoms of allergy by inhibiting release of chemical mediators such as histamine and leukotriene  $C_4$  through acting on mast cells, and by showing histamine  $H_1$  receptor antagonistic activity. It is usually used for the treatment of allergic rhinitis, urticaria and itch accompanied by skin diseases such as eczema, dermatitis and pruritus.

### Before 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.
- •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<</li>
- to be written by a healthcare professional>>
- For adults: In general, take 1 tablet (10 mg as the active ingredient) at a time, once daily after a meal. The dosage may be adjusted according to your disease, age and symptoms.

<u>For children aged 7 years old or over</u>: In general, take 1 tablet (10 mg as the active ingredient) at a time, once daily after a meal.

In each case, strictly follow the instructions.

- •If you miss a dose, take it as soon as you remember. If it is close to your next dose, skip the missed dose. 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

• If you are breastfeeding, avoid breastfeeding while taking this medicine.

#### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include sleepiness, malaise, pain in abdomen, dry mouth, nausea, vomiting, rash and constipation. 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.

- •turning into blue-purple to dark purple in skin and mucous membrane (especially lips and nails), breathlessness, dizziness on standing up, swelling of eyelids and/or mouth (lips) [shock, anaphylaxis]
- (patients with a history of epileptic seizures) muscle stiffness and tremor, disturbance of consciousness, loss of memory before seizures [epilepsy]
- spasmodic muscular contraction [convulsion]
- •malaise, loss of appetite, yellowness in skin or in the white of eyes [hepatic function disorder, 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 the medicine out of the reach of infants and children. Store it at room temperature (1 to 30 degrees Celsius) away from direct sunlight 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.