

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

Internal

Revised: 11/2018

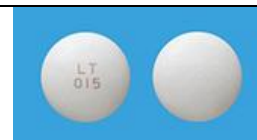
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name:Gaster Tablets 20mg

Active ingredient:Famotidine

Dosage form:white to faintly yellowish white tablet (diameter: 8.1mm, thickness: 4.0mm)

Imprint or print on wrapping:Before/ (Face) ガスター20mg, house-mark + 117, 20mg,
(Back) ガスター, 20mg, house-mark
After/ (Face)ガスター20mg, LT015, 20mg, (Back) ガスター, 20mg,
house-mark



Effects of this medicine

This medicine blocks the histamine₂ receptors of the gastric mucosa, thus suppresses the secretion of stomach acid. It is usually used in the treatment of gastric ulcer, duodenal ulcer, gastritis and esophagitis.

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))

•For the treatment of gastric ulcer, duodenal ulcer, anastomotic ulcer, upper gastrointestinal hemorrhage, reflux esophagitis, and Zollinger–Ellison syndrome: In general, for adults, take 1 tablet (20 mg of the active ingredient) at a time, twice daily (after breakfast, and after supper or before bedtime). You may also take 2 tablets (40 mg) at a time, once daily (before bedtime).

For the treatment of gastric mucosal lesions associated with acute gastritis and acute exacerbation of chronic gastritis: In general, for adults, take 10 mg at a time, twice daily (after breakfast, and after supper or before bedtime). You may also take 1 tablet (20 mg) at a time, once daily (before bedtime).

This preparation contains 20 mg of the active ingredient in 1 tablet. This preparation should be used when you are instructed to take 20 mg or 40 mg at a time according to the dosage regimen specified above.

The dosage may be adjusted according to your age or symptoms.

In any case, strictly follow the instructions.

- If you miss a dose, skip the missed dose and continue 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/eruption, hives, facial edema, constipation, irregular menstruation and gynecomastia. 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.

- facial pallor, cold sweat, dizziness on standing up [shock, anaphylaxis]
- sore throat, headache, muscle pain, symptoms of anemia, bleeding tendency [aplastic anemia, pancytopenia, agranulocytosis, hemolytic anemia, thrombocytopenia]
- fever, loss of appetite, red rash [mucocutaneo-ocular syndrome, toxic epidermal necrolysis]
- general malaise, loss of appetite, yellowing of the skin and the whites of the eye [hepatic function disorder, jaundice]
- muscle pain, feelings of weakness, brown urine [rhabdomyolysis]

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 infants and children. Store away from direct sunlight, heat and humidity.

•Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.