

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

Internal

Revised: 02/2016

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:Famotidine OD Tablets 20mg 「OHARA」

**Active ingredient:**Famotidine

**Dosage form:**white tablet, diameter: 8.6 mm, thickness: 3.6 mm

**Print on wrapping:**ファモチジン OD 20 mg 「オーハラ」, ファモチジン OD, 20 mg, 口腔内崩壊錠, Famotidine OD 20mg 「OHARA」, ファモチジン OD オーハラ



## Effects of this medicine

This medicine blocks histamine H<sub>2</sub> receptors of the cells of the stomach wall and suppresses the secretion of gastric acid.

It is usually used to treat gastric ulcer or reflux esophagitis and to improve gastric mucosal lesions associated with acute gastritis and acute exacerbation of chronic gastritis.

## 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 have heart disease, or renal or liver disorder.
- 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 gastric ulcer, duodenal ulcer, anastomotic ulcer, upper gastrointestinal bleeding (due to gastric ulcer, acute stress ulcer, hemorrhagic gastritis), reflux esophagitis, and Zollinger–Ellison syndrome: In general, for adults, take 1 tablet (20 mg of the active ingredient) at a time, twice a day, after breakfast, and after dinner or before bedtime. You may also take 2 tablets (40 mg) at a time, once a day before bedtime.  
For gastric mucosal lesions (erosion, bleeding, redness, edema) of acute gastritis and acute exacerbation of chronic gastritis: In general, for adults, take 10 mg of the active ingredient at a time, twice a day, after breakfast, and after dinner or before bedtime. You may also take 20 mg at a time, once a day before bedtime. This preparation contains 20 mg of the active ingredient.  
In any case, the dosage may be adjusted according to the disease, age/symptoms. Strictly follow the instructions.
- Swallow this medicine with saliva after crushing it lightly using your tongue. However, avoid taking this medicine when you are lying down. You can also take this medicine with water or lukewarm water in the same way as the common medicine.
- 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 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 constipation, rash/eruption, hives (erythema), facial edema, irregular menstruation, gynecomastia and galactorrhea. 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.**

- respiratory distress, generalized flushing, hives [shock, anaphylaxis]
- general malaise, subcutaneous/submucosal bleeding, fever [aplastic anemia, pancytopenia, agranulocytosis, hemolytic anemia, decreased platelets]
- high fever of 38 degrees Celsius or higher, bloodshot eyes, mucosal erosion of the lips/eyes [mucocutaneous ocular syndrome, toxic epidermal necrolysis]
- general malaise, loss of appetite, yellow discoloration of the skin and the white of eyes [liver dysfunction, jaundice]
- muscle pain, lassitude, reddish 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 moisture.
- Discard the remainder. Do not store them.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.

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