

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

Internal

Revised: 04/2010

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 D Tablets 20mg "SAWAI"

Active ingredient:Famotidine

Dosage form:white tablet, diameter: 8.5 mm, thickness: 3.6 mm

Imprint or print on wrapping:ファモチジン D, 20mg「サワイ」, SW-F20, 20mg,
Famotidine D 20mg



Effects of this medicine

This medicine suppresses secretion of gastric acid and pepsin by selectively blocking H₂ receptors on the parietal cells of the gastric mucosa.

It is usually used to treat gastric ulcer, duodenal ulcer, anastomotic ulcer, upper gastrointestinal bleeding, reflux esophagitis and Zollinger–Ellison syndrome, and to improve gastric mucosal lesions in patients with acute gastritis or acute exacerbation of chronic gastritis.

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 gastric ulcer, duodenal ulcer, anastomotic ulcer, upper gastrointestinal bleeding, 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. However, you may also take 2 tablets (40 mg) at a time, once a day before bedtime.
For improvement of gastric mucosal lesions in patients with acute gastritis or 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. However, you may also take 1 tablet (20 mg) at a time, once a day before bedtime.
In any case, the dosage may be adjusted according to the disease, age or symptoms. Strictly follow the instructions.
- You can moisten the tablet with saliva on your tongue, then crush it lightly with your tongue, and swallow the tablet with saliva. Do not take the tablet without water when you are lying down.
- 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. 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 (erythema), 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.

- respiratory distress, generalized redness accompanied by itching, facial edema [shock, anaphylactoid symptoms]
- general malaise, bruise, fever [pancytopenia, agranulocytosis, aplastic anemia, hemolytic anemia]
- fever, redness and swelling of the skin/mucosa with rash or blisters, conjunctival hyperemia [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 or limbs, 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 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.