Package leaflet: Information for the user

Famotidine 20 mg film-coated tablets
Famotidine 40 mg film-coated tablets

famotidine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Famotidine is and what it is used for
Famotidine works by reducing the amount of acid produced in the stomach. It is used to treat certain conditions caused by too much acid produced in the stomach. It is a gastrointestinal medicine that belongs to a group of medicine called Histamine H_2-receptor antagonists.

Famotidine is used for:
treatment of
- symptoms of reflux disease (mild reflux oesophagitis), such as heartburn (Famotidine 20 mg)
- mild to moderate inflammation of the oesophagus (food pipe) (Famotidine 40 mg)
- benign gastric ulcer
- duodenal ulcer
- prevention of recurrent duodenal ulcers (only with Famotidine 20 mg)
- treatment of Zollinger-Ellison-Syndrome. This is a condition caused by abnormal production of the hormone gastrin that causes an overproduction of stomach acid.

2. What you need to know before you take Famotidine
DO NOT take Famotidine
- if you are allergic to the famotidine or any of the other ingredients of this medicine (listed in section 6). If symptoms of hypersensitivity develop, Famotidine should be discontinued.
- Children should not be treated with Famotidine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Famotidine.
- **Tell your doctor immediately** if you notice any of the following symptoms:
  - an unintentional loss of weight
  - repeated vomiting
  - difficulty in swallowing
  - vomiting blood
  - you look pale and feel weak (anaemia)
  - you notice blood in your stools

Your doctor may decide that you need some tests to rule out malignant disease because famotidine also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

- if you are taking atazanavir for HIV infection (see 'Other medicines and Famotidine ' below).
- if you suffer from duodenal ulcers and benign gastric ulcers your doctor may decide that these have been caused by a bacterial infection with H.pylori. If this is the case you should undergo a special therapy under direction by the doctor to eliminate these bacteria.
- if you suffer from kidney (renal) impairment. Your doctor may prescribe you a lower dose of Famotidine (see 3. "How to take Famotidine ").
- and do not use Famotidine if you suffer from minor gastrointestinal complaints. Please ask your doctor.

Other medicines and Famotidine
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Please contact your doctor if you take any of the medicines mentioned below:

You should not take Famotidine

- if you take the substance probenecid (a medicine to treat gout) at the same time, because probenecid can delay the elimination of famotidine.
- in combination with atazanavir, ritonavir and tenofovir (medicines used to treat HIV infection)

The effect of Famotidine can be reduced by:

- medicines to neutralize the stomach acid (antacids). As the effect of Famotidine will be reduced, you should take Famotidine at least 1-2 hours before taking an antacid.
- sucralfate (medicine to treat ulcers). As a rule you should not take sucralfate within 2 hours of Famotidine.

Famotidine may reduce the effect of:

- ketoconazole or itraconazole (medicines to treat fungal infections). You should take ketoconazole 2hours before taking Famotidine.
- Atazanavir with ritonavir (medicines taken for HIV infection). Please ask your doctor.
- calcium carbonate, when used as a medicine for high blood phosphate levels (hyperphosphataemia) in patients on dialysis
- posaconazole oral suspension (a drinkable medicine used to prevent and treat some fungal infections).
- dasatinib, erlotinib, gefitinib, pazopanib (medicines used to treat cancer).

Famotidine with food and drink
Famotidine can be taken with or without food.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Famotidine can be used during pregnancy if necessary.

Breast-feeding
Famotidine is excreted in breast milk only in small amounts. Your doctor will decide whether you should take this medicine while breastfeeding.

Driving and using machines
It is not known whether Famotidine affects the ability to drive or to use machines. Do not drive or operate machines until you are sure that your ability is not affected.

3. How to take Famotidine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration:
Famotidine Clonmel should be swallowed whole with some liquid. It does not need to be taken at mealtimes.

The recommended dose depends on the severity of your disease and the dosage of previous medications. Your doctor will decide how much you should take.

Recommended doses are given below:

Treatment of symptoms of reflux disease (e.g. heartburn)

20 mg of famotidine twice a day.

Treatment of mild to moderate inflammation of the oesophagus (food pipe)
40 mg of famotidine twice a day.

Benign gastric ulcers and duodenal ulcers
40 mg of famotidine before going to sleep.

The therapy should last for 4 to 8 weeks. However, this period may be shortened if your doctor finds that the ulcer has healed (e.g. by an endoscopic examination). If the examination does not show that the ulcer has healed then treatment should be continued for another 4 weeks.

Prevention of recurrent duodenal ulcers
20 mg of famotidine in the evening.

The recommended maintenance dose of 20 mg has been continued effectively in clinical studies of 12 months duration.

Zollinger-Ellison syndrome
Providing there has not been previous therapy, the treatment starts with 20 mg of famotidine every 6 hours.

Depending on the acid secretion and your clinical response, your doctor may increase the dose as treatment continues until the desired acid levels have been reached. If treatment with a daily dosage of up to 800 mg doesn't work, your doctor may consider an alternative treatment to regulate acid secretion.

If you have previously undergone a treatment with similar medicines (e.g. other Histamine H_2 receptor antagonists) it is possible to start the treatment with Famotidine at a higher dosage than the initial dosage that is usually recommended. Ask your doctor about the right dosage.

Treatment should be continued for as long as necessary.

<u>Patients with impaired kidney (renal) function</u>
If you suffer from impaired renal function your doctor may reduce the daily dose to 50%. Dialysis patients should also take dosages that are reduced to 50%. Famotidine should be administered at the end of dialysis or thereafter since some of the active ingredient is removed via dialysis.

If you take more Famotidine than you should
Contact your doctor or the nearest hospital immediately. Your doctor will make efforts to inhibit absorption and relieve symptoms. Up to now there are no reports of overdosing with the active ingredient famotidine.

If you forget to take Famotidine
If you forget to take a dose, take one as soon as you remember and continue as before. Do not take a

double dose to make up for a forgotten dose. If you are concerned about missing your dose ask your doctor for advice.

If you stop taking Famotidine
Talk to your doctor if you wish to stop taking Famotidine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

If the following happens, stop taking the medicine and contact your doctor immediately or go to the casualty department at your nearest hospital:

Very rare side-effects (may affect up to 1 in 10,000 people)
- serious allergic/hypersensitivity reactions which causes difficulty in breathing or dizziness (anaphylaxis), swelling of the face or throat (angioneurotic oedema), difficulty in breathing or wheezing (bronchospasm)

Not known (frequency cannot be estimated from the available data)
- severe skin rash with blistering (Stevens-Johnson syndrome / toxic epidermal necrolysis)

The following side effects have been reported:

Common side-effects (may affect up to 1 in 10 people):
- headache
- dizziness
- constipation (obstipation)
- diarrhoea

Uncommon side-effects (may affect up to 1 in 100 people):
- dry mouth
- nausea, vomiting
- gastrointestinal complaints
- excessive internal gas (flatulence)
- loss of appetite
- rash, itching (pruritus)
- tiredness (fatigue)

Rare side-effects (may affect up to 1 in 1,000 people):
- serious allergic/hypersensitivity reactions which causes difficulty in breathing or dizziness (anaphylaxis), swelling of the face or throat (angioneurotic oedema), difficulty in breathing or wheezing (bronchospasm)
- yellowing of the skin or the whites of the eyes caused by blockade of bile flow (jaundice caused by intrahepatic cholestasis)
- hives (urticaria)
- joint pain (arthralgia)
- increase in laboratory values (transaminases, gamma GT, alkaline phosphatase, bilirubin)

Very rare side-effects (may affect up to 1 in 10,000 people):
- changes in the blood: a fall in the number of all types of blood cells (pancytopenia) or a fall in the number white blood cells (leukopenia, agranulocytosis) or blood platelets (thrombocytopenia), which can cause e.g. weakness, fatigue, sudden fever, sore throat, bruising or nose bleed.
- reversible psychological disturbances (e.g. hallucinations, disorientation, confusion, anxiety, agitation, depression)
- tingling or numbness in the hand or feet (paraesthesia)
- drowsiness

- sleeplessness
- epileptic seizures (grand mal)
- hair loss
- muscle cramps
- impotence, reduced libido
- feelings of tightness in the chest

Not known (frequency cannot be estimated from the available data)
- inflammation of the liver (hepatitis)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Famotidine
Keep this medicine out of the sight and reach of children.

Famotidine 20 mg and 40 mg: This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and outer packaging after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information
What Famotidine contains
The active substance is famotidine.

Famotidine 20 mg film-coated tablets:
Each film-coated tablet contains 20 mg of famotidine.

Famotidine 40 mg film-coated tablets:
Each film-coated tablet contains 40 mg of famotidine.

The other ingredients for the 20 mg product are pregelatinised starch, microcrystalline cellulose, talc, magnesium stearate, hypromellose, macrogol, titanium dioxide (E171), iron oxide red, iron oxide yellow, iron oxide black (E172)

The other ingredients for the 40mg product are pregelatinised starch, microcrystalline cellulose, talc, magnesium stearate, Iron oxide red (E172), hypromellose, Calcium carbonate (E170), macrogol, carmine (E120)

What Famotidine looks like and contents of the pack
The Famotidine 20 mg Tablets are Hexagonal, biconvex, brown film-coated tablets.

The Famotidine 40 mg Tablets are Circular, biconvex, pink to pinkish film-coated tablets with a break line on one side.

PVC-Aluminium-blisters with 7, 10, 14, 20, 21, 28, 30, 50, 56, 60, 100 film-coated tablets
Not all pack sizes may be marketed.

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Amdipharm Ltd.
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Manufacturer:
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This leaflet was last revised in April 2025.