



**Package leaflet:
Information for the patient**

**Famotidine 20 mg
Film-coated Tablets**
**Famotidine 40 mg
Film-coated Tablets**

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 Tablets are and what they are used for
2. What you need to know before you take Famotidine Tablets
3. How to take Famotidine Tablets
4. Possible side effects
5. How to store Famotidine Tablets
6. Contents of the pack and other information

1. What Famotidine Tablets are and what they are used for

Famotidine belongs to a group of medicines called histamine H₂ antagonists, which reduce the amount of acid in the stomach.

Famotidine 20 mg Tablets are used:

- to treat ulcers of the stomach and small intestine (duodenum)
- to prevent ulcers of the small intestine (duodenum) recurring
- to treat Zollinger-Ellison Syndrome, a condition where the stomach produces too much acid
- to treat the symptoms (e.g. heartburn) of mild reflux oesophagitis (mild inflammation of the gullet).

Famotidine 40 mg Tablets are used:

- to treat ulcers of the stomach and small intestine (duodenum)

• to treat Zollinger-Ellison Syndrome, a condition where the stomach produces too much acid

• to treat mild to moderate reflux oesophagitis (mild to moderate inflammation of the gullet), a condition which causes heartburn.

2. What you need to know before you take Famotidine Tablets

Do not take Famotidine Tablets

- if you are allergic to famotidine or any of the other ingredients of this medicine (listed in section 6).
- if you have had an allergic reaction to another histamine H₂ receptor antagonist in the past, as cross sensitivity has been observed in this substance class.

Warnings and precautions

Talk to your doctor before taking Famotidine Tablets:

- if you have kidney problems (see section 3, 'How to take Famotidine Tablets', below)
- if you are taking atazanavir for HIV infection (see 'Other medicines and Famotidine Tablets' below).

Famotidine is not suitable for the treatment of minor, transient symptoms.

Your doctor may also carry out further investigations to exclude cancer if you suffer from a gastric ulcer. Please especially report to your doctor symptoms such as:

- unintentional weight loss
- repeated vomiting
- difficulty swallowing
- vomiting blood
- looking pale and feeling weak (anaemia)
- blood in your stools.

Some ulcers may be due to a bacterium called *Helicobacter pylori*. Your doctor will carry out some tests to determine if you need additional treatment for this infection to help your ulcer to heal.

Children

No sufficient experience has been gained on the safety and efficacy of famotidine in children. Therefore children should not be treated with famotidine.

Other medicines and Famotidine Tablets

Do not take Famotidine Tablets in combination with:

- probenecid (used to treat gout)
- atazanavir in combination with ritonavir and tenofovir (for HIV infection).

Talk to your doctor if you are taking any of the following (also see 'Taking in combination with other medicines' in section 3 'How to take Famotidine Tablets'):

- antacids (used to treat excessive stomach acid)
- ketoconazole, itraconazole (used to treat severe fungal infections).
- sucralfate (used to treat ulcers of the gut)
- atazanavir with ritonavir (for HIV infection)
- calcium carbonate, when used as a medicine for high blood phosphate levels (hyperphosphataemia) in patients on dialysis.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Famotidine may decrease the effect of posaconazole oral suspension (a drinkable medicine used to prevent and treat some fungal infections)
- Famotidine may decrease the effect of dasatinib, erlotinib, gefitinib, pazopanib (medicines used to treat cancer).

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

Experience with the use of famotidine during pregnancy is limited. If you are pregnant, you may only take Famotidine Tablets if your doctor considers the benefits of taking the tablets to be greater than the possible risks to your unborn child.

Breast-feeding

Famotidine, the active substance contained in Famotidine Tablets, passes into human milk. As there is no known information about the effects of famotidine on the infant when absorbed and impaired stomach acid secretion cannot be ruled out, you should not breast-feed during treatment. In consultation with your doctor, you may have to stop taking Famotidine Tablets.

Driving and using machines

Some patients have experienced side effects such as dizziness and headache while taking Famotidine Tablets. You should therefore avoid driving vehicles or operating machinery or doing activities which require prompt vigilance if you experience these symptoms (see section 4, 'Possible side effects').

3. How to take Famotidine Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you see another doctor or go into hospital, let the doctor or staff know what medicines you are taking.

The recommended dose is:

Adults (including the elderly)

Famotidine 20 mg Tablets

- **Treatment of ulcers of the stomach or small intestine:** Two 20 mg tablets taken in the evening before going to bed. Treatment may last 4 to 8 weeks.

- **To prevent ulcers of the small intestine recurring:**

One 20 mg tablet taken in the evening.

Your doctor will decide how long your treatment will last.

- **Zollinger-Ellison Syndrome:**

Usually one 20 mg tablet taken every 6 hours, but your doctor may adjust this dose, based on your response to the medicine.

Your doctor will decide how long your treatment will last.

- **Symptoms (e.g. heartburn) of mild reflux oesophagitis:**

One 20 mg tablet should be taken two times a day.

Treatment usually lasts for 6 weeks, but your doctor may continue your treatment for up to 12 weeks.

Famotidine 40 mg Tablets

- **Treatment of ulcers of the stomach or small intestine:**

One 40 mg tablet taken in the evening before going to bed.

Treatment may last 4 to 8 weeks.

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- Zollinger-Ellison Syndrome:** Usually 20 mg taken every 6 hours. For this dose Famotidine 20 mg is available. Your doctor may adjust this dose and prescribe Famotidine 40 mg for this condition, based on your response to the 20 mg tablets. Your doctor will decide how long your treatment will last.

- Mild to moderate reflux oesophagitis:** Usually one 40 mg tablet should be taken two times a day. Your doctor may adjust this dose based on your response to treatment. Treatment usually lasts for 6 weeks, but your doctor may continue your treatment for up to 12 weeks.

Patients with impaired kidney function

Your doctor may prescribe a lower dose. If you suffer from a severely impaired kidney function, the dose is usually halved.

Use in children

Famotidine must not be taken by children.

How you should take Famotidine Tablets

The tablets should be swallowed preferably with a drink of water.

Taking in combination with other medicines:

The following medicines may affect the absorption of Famotidine Tablets if they are taken at the same time.

- Antacids:** Take Famotidine Tablets at least 1 to 2 hours before taking an antacid.
- Ketoconazole or Itraconazole:** Take Famotidine Tablets at least 2 hours after taking Ketoconazole or Itraconazole.
- Sucralfate:** Take Famotidine Tablets at least 2 hours before or 2 hours after taking Sucralfate.

If you take more Famotidine Tablets than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Famotidine Tablets

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

Regular intake of famotidine - in accordance with the dosage recommendations and instructions of the doctor - contributes significantly to the success of treatment.

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 tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

Very rare: may affect up to 1 in 10,000 people

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- a severe blistering rash in which the surface layers of the skin peel (Stevens Johnson syndrome/toxic epidermal necrolysis)

You may need urgent medical attention or hospitalisation.

The following side effects have been reported at the approximate frequencies shown:

Common: may affect up to 1 in 10 people

- headache
- dizziness
- constipation
- diarrhoea

Uncommon: may affect up to 1 in 100 people

- loss of appetite
- taste disorder
- dry mouth
- stomach problems, nausea, vomiting, excessive intestinal gas
- skin rash
- itching
- nettle rash
- tiredness

Rare: may affect up to 1 in 1,000 people

- joint pain
- abnormal blood test results

Very rare: may affect up to 1 in 10,000 people

- blood disorders which may be characterised by fever or chills, sore throat, unusual bleeding or unexplained bruising, ulcers in your mouth or throat
- depression
- anxiety
- agitation
- disorientation
- confusion
- hallucinations
- difficulty falling or staying asleep
- decrease in sexual desire
- epileptic fits
- pins and needles or numbness
- drowsiness
- a lung disease characterized by progressive scarring of the lungs (interstitial pneumonia)
- liver enzyme abnormalities
- yellowing of the skin and whites of the eyes (hepatitis)
- hair loss
- muscle cramps
- impotence (inability to achieve or maintain an erection)
- feeling of tightness in the chest

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Famotidine Tablets

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Famotidine Tablets contain

- The active substance is famotidine. Each 20 mg film-coated tablet contains 20 mg of famotidine. Each 40 mg film-coated tablet contains 40 mg of famotidine.
- The other ingredients are microcrystalline cellulose, pregelatinised starch, hydroxypropyl cellulose, magnesium stearate, hypromellose, talc, titanium dioxide, yellow iron oxide, red iron oxide

What Famotidine Tablets look like and contents of the pack

Famotidine 20 mg Tablets are yellow, square, biconvex, film-coated tablets with slightly rounded edges, approximately 5.2 mm in size, debossed with "F1" on one side and plain on the other side. Famotidine 40 mg Tablets are brown, square, biconvex, film-coated tablets with slightly rounded edges, approximately 7.3 mm in size, debossed with "F2" on one side and plain on the other side. Famotidine Tablets are available in packs of 28 tablets.

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If you are blind or partially sighted and require this leaflet in a different format, call 0800 669 6825 or contact medinfo@celixpharma.com.

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Reviewed / Approved by

Sign / Date

Product Description

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CCR No.

Artwork Creation Date

04 October 2024

Colors

Printing Colors (Pantone/CMYK)

Technical Colors (Non-printable colors)

Black

Dimension

Font Size (Minimum)

9 pt

Font Type

Myriad Pro

Component

PIL

Market

UK

Pharmacode

Dummy