Fonts Size :

Generic Name font size : 12 pt.

Remaining fonts size : 9 pt.

150 mm

350 mm

PHARMA CODE

XXXX

Pharmacode Reading Direction

PACKAGE LEAFLET: INFORMATION FOR THE USER

Famotidine 20mg film-coated tablets
Famotidine 40mg 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Famotidine 20mg and 40mg film-coated tablets are referred as famotidine tablets in this leaflet.

What is in this leaflet

1. What famotidine is and what it is 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 is and what it is used for

Famotidine belongs to a group of medicines called H2−receptor antagonists. These work by reducing the amount of acid you produce in your stomach.

Famotidine is used to treat the following:
- Stomach ulcers (gastric/duodenal ulcers)
- Mild to moderate irritation and inflammation caused by stomach acid leaking up into the gullet (reflux oesophagitis)
- Zollinger Ellison Syndrome (a rare disorder that involves recurrent ulcers and tumours in the stomach and intestines)

2. What you need to know before you take famotidine tablets

Do not take famotidine tablets if:
You are allergic to famotidine, other H2−receptor antagonists or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:
Talk to your doctor, pharmacist or nurse before taking famotidine tablets if:
- There is a possibility of a malignant growth (tumour) being present in your stomach
- You have kidney problems
- You have been taking famotidine for a long time. Your doctor may monitor your blood count and liver function.

Other medicines and famotidine tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without prescription. This includes herbal medicines.
Medicines which may interact with famotidine
- 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)
- Ketoconazole (should be administered 2 hours before famotidine) or Itraconazole, used to treat fungal infections
- Probenecid used to treat gout. Probenecid can cause an increase in famotidine levels.
- Antacids, for indigestion (famotidine should be administered 1-2 hours before taking an antacid)
- Sucralfate, used to treat and prevent the recurrence of ulcers (sucralfate should not be administered within 2 hours of taking famotidine)
- Calcium carbonate, when used as a medicine for high blood phosphate levels in patients on dialysis
- Atazanavir, used for treatment of HIV infection

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 for advice before taking this medicine.

Pregnant
If you are pregnant or suspect you are pregnant, you should not take famotidine tablets unless your doctor thinks the benefits outweigh the risks.

Breast-feeding
If you are breast−feeding, you should either stop taking famotidine tablets or stop breast-feeding as it is excreted in breast milk

Driving and using machines
Whilst taking famotidine tablets you may feel dizzy or have a headache. If you develop these symptoms, you should not drive or operate machinery or do activities which require you to be alert and have quick reactions.

Information on sodium content
This medicine contains less than 1 mmol (23mg) sodium per tablet, that is to say essentially 'sodium -free'.

3. How to take famotidine tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- These tablets are to be taken orally.
- The score line is only there to help you break the tablet if you have difficulty swallowing it whole.
- Famotidine tablets can be taken with or without food.

Adults and Elderly
Stomach Ulcers
- The recommended dose is 40mg once a day at night.
- The duration of treatment will normally be between 4−8 weeks. In most cases the ulcer will heal with this treatment within 4 weeks. If your ulcer has not healed completely, treatment may be continued for another 4 weeks.
- For treatment of a recurrent ulcer, the recommended dose is 20mg at night.

Zollinger Ellison Syndrome
The recommended dose is 20mg every six hours. The dosage should then be adjusted.

Reflux Oesophagitis
- The recommended dose for treating mild symptoms is 20mg twice a day.
- The recommended dose for treating mild to moderate symptoms is 40mg twice a day.
- Treatment should be continued for 6−12 weeks.

Patients with Kidney disorders/on dialysis
- If you have kidney disorders, your doctor is likely to reduce your dose.
- Famotidine tablets should be administered at the end of dialysis or after since some of the active ingredient is removed by dialysis.

Use in children
Famotidine tablets are not recommended for children.

If you take more famotidine tablets than you should
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice. Remember to take this leaflet or any remaining tablets with you.

If you forget to take your famotidine tablets
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you stop taking famotidine tablets
It is important that you keep taking famotidine tablets for as long as your doctor has told you to.

In case of long-standing ulcer disease, abrupt withdrawal after symptom relief should be avoided.

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

4. Possible side effects

Like all medicines, famotidine tablets can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following symptoms:
- Allergic reactions: swelling of the face throat or tongue, difficulty in breathing or dizziness (anaphylaxis)
- Difficulty in breathing or wheezing (bronchospasm)
- Severe blistering of the skin, mouth, eyes and genitals (Stevens Johnson syndrome, toxic epidermal necrolysis)
- Shortness of breath or dry cough due to inflammation of the lungs (interstitial pneumonia)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioneurotic oedema)

Common side effects (may affect up to 1 in 10 people)
- Headache
- Dizziness
- Constipation
- Diarrhoea

Uncommon side effects (may affect up to 1 in 100 people)
- Feeling and/or being sick (nausea/vomiting)
- Abdominal pain
- Excessive wind/feeling bloated (flatulence)
- Tiredness (fatigue)
- Dry mouth
- Loss of appetite (anorexia)
- Taste disorder
- Severe itching (pruritus)
- Rash
- Skin rashes with the formation of wheals (urticaria)

Rare side effects (may affect up to 1 in 1,000 people)
- An increase in liver enzymes in the blood (detected through blood tests)

Very rare side effects (may affect less than 1 in 10,000 people)
- Reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- Reduction in white blood cells (leukopenia, neutropenia),
- Reduction in white blood cells which may make infections more likely (agranulocytosis)
- Reduction in blood cells which can cause weakness, bruising or make infections more likely (pancytopenia)
- Reversible psychic disturbances including:

-Hallucinations (seeing or hearing things that are not real)
-Disorientation
-Confusion
-Anxiety disorders
-Restlessness (agitation)
-Depression
-Disorders of sexual function (reduced libido)
-Difficulty in sleeping (insomnia)

- Inability to maintain an erection (impotence)
- Tingling or numbness in the hands or feet (paraesthesia)
- Sleepiness or drowsiness (somnolence)
- Fits (convulsions), epileptic seizures including 'grand mal seizures (particularly in patients with kidney problems)
- Hair loss (alopecia)
- Chest tightness
- Muscle cramps
- Joint pain (arthralgia)
- Inflammation of liver (hepatitis)
- Yellowing of the skin and whites of the eyes (jaundice)
- Abnormal liver function tests
- Worsening of existing liver disease
- Abnormal heart rhythm where the heart beats too slowly (AV block)
- Disrupted heart rhythm/irregular heartbeat (arrhythmias)
- Heart rhythm condition that may cause a fast heartbeat (QT prolongation) (especially in patients with impaired kidney function)

Other side effects
Enlargement of breasts in men (gynaecomastia) (not known if caused by famotidine)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at 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 famotidine after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.
- This medicinal product 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 to protect the environment.

6. Contents of the pack and other information

What Famotidine tablets contains
- Each film-coated tablet contains 20mg or 40mg of famotidine.

The other ingredients are: maize starch, microcrystalline cellulose (PH 101), sodium starch glycolate (Type-A), povidone K30, magnesium stearate.

The coating material contains:
For 20mg-Opadry 03H28758 White:hypromellose, titanium dioxide, talc, propylene glycol

For 40mg- Opadry 03H520034 Yellow: hypromellose, titanium dioxide, talc, propylene glycol, iron oxide yellow

What famotidine tablets look like and contents of the pack

Famotidine 20mg film-coated tablets are white film coated, round shaped biconvex, tablet, debossed with "FT" & "20" separated by breakline on one side and plain on other side. The tablets have diameter of 6.10 mm and thickness 3.40 mm.

Famotidine 40mg film-coated tablets are yellow film-coated, round shaped biconvex, tablet, debossed with "FT" & "40" separated by breakline on one side and plain on other side. The tablets have diameter of 8.10 mm and thickness 4.20mm.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

The tablets are packed in Aluminium- PVC White Opaque film and Aluminium- PVC/PVDC White Opaque film blisters of 5, 7, 10, 14, 15, 20, 28, 30, 49, 50, 56, 60, 90, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder
Flamingo Pharma (UK) Ltd.
First Floor, Kirkland House,
11-15 Peterborough Road,
Harrow, Middlesex, HA1 2AX,
United Kingdom.

Manufacturer
Flamingo Pharma (UK) Limited
The Bloc, 38 Springfield Way,
Anlaby, Hull,HU10 6RJ,
United Kingdom

To request a copy of this leaflet in Braille, large print or audio please call free of charge: 0800 198 5000 (UK only). Please be ready to give the following information:
Product Name: Famotidine 20mg and 40mg film-coated tablets
Reference Number: PL 43461/0165 and PL 43461/0166
This is a service provided by the Royal National Institute of Blind People

This leaflet was last revised in 02/2026.

POM

MPLLFAMXXXXTBCOM
FPLXXX433V01_A