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, pharmacist or nurse.
- 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, pharmacist or nurse. 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
2. What you need to know before you take Famotidine
3. How to take Famotidine
4. Possible side effects
5. How to store Famotidine
6. Contents of the pack and other information

1. What Famotidine is and what it is used for

Famotidine 20 mg and 40 mg film-coated tablets (referred to as Famotidine in this leaflet) 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

Do not take Famotidine 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 if:
- there is a possibility of a **malignant growth (tumour)** being present in your stomach.
- you have **kidney problems**.
- you have been taking **a high dose of famotidine for a long time**. Your doctor may monitor your blood count and liver function.

Other medicines and Famotidine

Tell your doctor, pharmacist or nurse 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
- **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, pharmacist or nurse for advice before taking this medicine.

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

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

Driving and using machines
Whilst taking famotidine 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.

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

3. How to take Famotidine

Always take famotidine exactly as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are not sure.

- These tablets are to be taken orally.
- Famotidine can be taken with or without food.

Adults and Elderly

Stomach Ulcers
- The recommended dose is 40 mg 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 20 mg at night.

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

Reflux Oesophagitis
- The recommended dose for treating mild symptoms is 20 mg twice a day.
- The recommended dose for treating mild to moderate symptoms is 40 mg 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 should be administered at the end of dialysis or after since some of the active ingredient is removed by dialysis.

Use in children
Famotidine **is not** recommended for children.

If you take more Famotidine 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 Famotidine
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
It is important that you keep taking Famotidine 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, pharmacist or nurse.

4. Possible side effects

Like all medicines, famotidine 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 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 at http://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

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

This medicinal product does not require any special storage conditions.

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

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 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 are:
Tablet core: cellulose, microcrystalline (PH 101), maize starch, sodium starch glycolate, hydroxypropyl cellulose, cellulose, microcrystalline (PH 102) and magnesium stearate.

Tablet coat:
Famotidine 20 mg film-coated tablets:
Hydroxypropyl cellulose (E463), hypromellose (E464), titanium dioxide (E171) and iron oxide yellow (E172).

Famotidine 40 mg film-coated tablets:
Hydroxypropyl cellulose (E463), hypromellose (E464) and titanium dioxide (E171).

What Famotidine looks like and contents of the pack

Famotidine 20 mg film-coated tablets:
Light yellow to yellow, round, approximately 6 mm in diameter, film coated tablets debossed with “11” on one side and plain on the other side.

Famotidine 40 mg film-coated tablets:
White, round, approximately 8 mm in diameter, film-coated tablets, debossed with “12” on one side and plain on the other side.

10, 20, 28, 30, 50, 56, 60, 90 or 100 film-coated tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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