Package leaflet: Information for the patient

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

famotidine

(Referred to as Famotidine tablets in this leaflet)

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 tablets are and what they are used for

Famotidine tablets contain the active substance famotidine. Famotidine belongs to a group of medicines called H_2-receptor antagonists. These work by reducing the amount of acid you produce in your stomach.

Famotidine tablets are 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 H_2-receptor antagonists or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor before taking Famotidine tablets if:

- There is a possibility of a malignant growth (tumour) being present in your stomach.
- You suffer from 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.

Children

The use of famotidine in children is not recommended because there is not enough information about its use in this age group.

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.
- Antacids, for indigestion (famotidine should be administered 1 to 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.

Pregnancy

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 famotidine 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.

Famotidine 40 mg film-coated tablets contain carmoisine (E122) aluminium lake. Carmoisine may cause allergic reactions.

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.

- Swallow your Famotidine tablets with a drink of water
- The tablets can be taken with or without food
- Each 40 mg tablet has a score line on one side. The tablet can be divided into equal doses by breaking it along the score line (each half of the tablet will contain 20 mg famotidine).

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 to 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 to 12 weeks.

Patients with kidney disorders/on dialysis

- If you suffer from a kidney disorder, 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 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 your 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.

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4. Possible Side Effects

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

Some side effects could be serious. Seek medical advice immediately if you develop any of 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)

These serious side effects are very rare.

Other possible side effects

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 (pruritis)
- Rash
- Skin rash 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 up to 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 psychiatric disturbances including:
  - Hallucinations (seeing or hearing things that are not real)
  - Disorientation
  - Confusion
  - Anxiety disorders
  - Restlessness (agitation)
  - Depression
  - Difficulty in sleeping (insomnia)
  - Disorders of sexual function (reduced libido)
- 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 the 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 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

Famotidine 20 mg film-coated tablets: this medicine does not require any special storage conditions.
Famotidine 40 mg film-coated tablets: store below 25°C.

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 strips after "EXP" (= do not use after). You should see a month and a year. The last day of that month is the expiry date.

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 contain:

- The active substance is famotidine.
  Each Famotidine 20 mg film-coated tablet contains 20 mg of famotidine.
  Each Famotidine 40 mg film-coated tablet contains 40 mg of famotidine.
- The other ingredients are: pregelatinized starch, microcrystalline cellulose (E460), talc (E553b), magnesium stearate (E470b) and red iron oxide (E172).
  The brown coating of Famotidine 20 mg film-coated tablets contains: hypromellose (E464), talc (E553b), macrogol (E1521), titanium dioxide (E171) and yellow, red, and black iron oxide (E172).
  The pink coating of Famotidine 40 mg film-coated tablets contains: hypromellose (E464), macrogol (E1521), titanium dioxide (E171), indigo carmine (E132) aluminium lake, D&C Yellow No.10 aluminium lake and carmoisine (E122) aluminium lake.

What Famotidine tablets look like and contents of the pack

Famotidine 20 mg film-coated tablets are brown, hexagonal, biconvex film-coated tablets, with a diameter of 7 mm point to point and 6.2 mm edge to edge.
Famotidine 40 mg film-coated tablets are pink, round, biconvex film-coated tablets with a diameter of 8 mm with a score line on one side. The 40 mg film-coated tablet can be divided into equal halves.

The tablets are supplied in blister packs of 28, 30 or 90 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
DHP Healthcare Ltd
13 Hanover Square, London W1S 1HN
United Kingdom

Manufacturer
QP-Services UK Limited
46 High Street, Yatton
Bristol BS49 4HJ
United Kingdom

Other Formats
To request a copy of this leaflet in Braille, large print or audio please call 0330 1359 454

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