PACKAGE LEAFLET

Package leaflet: Information for the patient

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
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 belongs to a group of medicines called histamine (H_2) antagonists or anti-ulcer medicines. These anti-ulcer medicines control the levels of acid in the stomach. Famotidine can lower the amount of acid you produce in your stomach.

Famotidine can be used for the following:
- To help treat non-cancerous stomach ulcers and ulcers in the first part of your intestine (duodenal ulcers)
- To help prevent the return of ulcers in the first part of the intestine
- To help treat Zollinger-Ellison syndrome (with a condition caused by too much stomach acid)
- To help treat acid reflux (burning pain caused by stomach acid escaping back up the food pipe) and the symptoms of an inflamed food pipe (oesophagitis)

2. What you need to know before you take Famotidine

Do not take Famotidine if:
- you are allergic to famotidine or any of the ingredients of this medicine (listed in section 6) or to any other medicines called H_2 antagonists

Warnings and precautions

Talk to your doctor or pharmacist before taking Famotidine if:
- you have kidney problems

Famotidine may hide the symptoms of other diseases. Your doctor may carry out tests to diagnose your condition and/or exclude other diseases before you start taking Famotidine.

During treatment

If you take a high dose for a long time your doctor may carry out blood tests to check your blood cells and liver function.

Children and adolescents
Famotidine should not be given to children or adolescents

Other medicines and Famotidine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially any of the following:

- itraconazole or ketoconazole, medicines used to treat fungal infections. Take ketoconazole 2 hours before your famotidine dose
- probenecid, a medicine used to treat gout
- antacids. Take your famotidine dose one to two hours before an antacid
- sucralfate, a medicine used for stomach ulcers. Do not take sucralfate within two hours of your famotidine dose
- atazanavir, used in the treatment of HIV
- calcium carbonate, when used as a medicine for high blood phosphate levels (hyperphosphataemia) in patients on dialysis
- 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

Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, talk to your doctor first before taking this medicine. If you do get pregnant while taking famotidine you must tell the doctor straightaway.

Breast-feeding
Famotidine passes into breast milk. If you are breast-feeding or planning to breast feed, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Do not drive or operate machines if you feel dizzy or get a headache while taking famotidine.

Famotidine contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Famotidine

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

Famotidine Tablets can be taken before or after food.

Use in adults (including the elderly)
Non-cancerous stomach or intestinal ulcers - The recommended dose is 40 mg of famotidine taken at night. In some cases treatment may last for up to 8 weeks.
To prevent intestinal ulcers from returning - The recommended dose is 20 mg of famotidine at bedtime.

To treat Zollinger-Ellison syndrome - The recommended starting dose is 20 mg of famotidine every 6 hours. Your doctor may need to increase this dose further depending how well the ulcers are healing. If you have already been taking a similar medicine or your symptoms are severe, your doctor may start you on a higher dose of famotidine.
To treat mild symptoms of oesophagitis (inflammation of the food pipe)**, due to acid reflux** - The recommended dose is 20 mg of famotidine twice daily.
Treatment usually lasts for 6 weeks, but if necessary, for 12 weeks.
To treat more severe symptoms of oesophagitis (inflammation of the food pipe) - The recommended dose is 40 mg of famotidine twice daily. Treatment usually lasts for 6 weeks, but if necessary, for 12 weeks.

Use in people with kidney problems
If you suffer from kidney problems, your doctor may give you a lower dose of famotidine. If you are having dialysis, your doctor may advise you to take a 20 mg tablet after dialysis.

Use in children and adolescents
Famotidine should not be given to children or adolescents.

If you take more Famotidine than you should
If you take too much of your medicine contact your doctor or go straight to the nearest hospital emergency department immediately.

If you forget to take Famotidine
If you forget to take your dose of Famotidine, unless it is almost time for your next dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Famotidine
If you have had stomach or intestinal ulcers for a long time you should not stop taking Famotidine if you feel better, without asking for advice from your doctor first.

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.

Stop taking Famotidine and contact your doctor or go to your nearest hospital emergency department immediately if you notice any of the following:

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

- a serious allergic reactions including rash, itching or hives, shortness of breath, wheezing or trouble breathing, or swelling of the face, hands, feet, mouth, throat or eyes.
- yellowing of the skin or whites of the eyes, dark urine, pale stools, persistent lack of appetite or abdominal pain which may be signs of serious liver problems.
- a severe blistering rash with bleeding in the lips, eyes, mouth, nose and genitals or severe skin reactions which starts with painful red areas or severe skin reactions which starts with painful red areas, then large blisters and ends with peeling of the surface layers of the skin. You may have Stevens-Johnson syndrome or condition known as Toxic Epidermal Necrolysis (TEN), which may be life-threatening.
- a burning sensation in the chest, shortness of breath and a persistent cough (these may be signs you have a lung infection (pneumonia) which may be severe). You may also get tired, have blue lips or fingertips (cyanosis) or lose weight.
- fits or seizures where you may lose consciousness, cry out or have jerky movements,

feel a warning (aura) beforehand and afterwards may be confused, tired or have a severe headache. If you have kidney problems you are more at risk of seizures.
- changes to the electrical activity of the heart seen on an EEG. You may feel light headed. Patients given this type of medicine by injection, have experienced some changes in heart rhythm or an irregular heart beat

Stop taking Famotidine and contact your doctor as soon as possible if you notice any of the following:

Very rare (may affect up to 1 in 10,000 people)
- an increase in the number of infections, you may get such as fever, severe chills, sore throat or mouth ulcers (these may be the signs that you have a low number of white blood cells in the body)
- low numbers of other blood cells, causing tiredness, shortness of breath, coldness in your hands and feet and pale skin (low number of red blood cells), unusual bruising or bleeding more easily than normal, difficulty in healing after a cut (low number of platelets)
- depression, confusion, feeling disorientated, anxious or agitated, or seeing, hearing or feeling things that are not real (hallucinations)

Other side effects

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

Uncommon (may affect up to 1 in 100 people)
- dry mouth
- feeling unusually tired
- feeling or being sick
- loss of appetite
- changes in taste
- wind
- feeling bloated
- itchy skin or rash

Rare (may affect up to 1 in 1,000 people)
- an increase in liver enzymes in the blood, seen in a blood test
- enlarged breasts in men. However it is not certain this effect is caused by famotidine.

Very rare (may affect up to 1 in 10,000 people)
- difficulty getting or maintaining an erection or a reduction in your sex drive
- tingling or numbness in the fingers and toes
- difficulty sleeping
- drowsiness
- chest tightness
- a change in blood liver enzymes seen in a blood test
- hair loss
- joint pain or muscle cramps

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 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

Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package in order to protect from light and moisture.
- Do not use this medicine after the expiry date which is stated on the label. 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 help protect the environment.

6. Contents of the pack and other information

What Famotidine contains

Each film-coated tablet contains either 20 mg or 40 mg of the active ingredient famotidine. The other ingredients are microcrystalline cellulose, pregelatinised starch, talc, magnesium stearate. The coating contains lactose monohydrate (see section 2 “Famotidine contains lactose”), hypromellose, titanium dioxide (E171) and triacetin. The 40 mg film-coated tablet coating also contains iron oxide yellow (E172) and iron oxide red (E172)

What Famotidine looks like and contents of the pack

The 20 mg film-coated tablets are white, ‘D’ shaped with two sides that curve out, marked 'FD/20' on one side and 'G' on the other.

The 40 mg film-coated tablets are light brown, diamond shaped with two sides that curve out, marked 'FD40' on one side and 'G/G' on the other. Famotidine Tablets are available in blister packs of 10, 20, 28, 30, 50, 56, 60, 90 or 100 film-coated tablets. Your pharmacist will dispense the number of tablets prescribed by your doctor.

Marketing Authorisation Holder

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