

PACKAGE LEAFLET: INFORMATION FOR THE USER

FAMOTIDIN

20 mg film coated tablets

FAMOTIDINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Famotidine is and what it is used for
2. Before you take Famotidine tablets
3. How to take Famotidine tablets
4. Possible side effects
5. How to store Famotidine tablets

1. WHAT FAMOTIDINE IS AND WHAT IT IS USED FOR

Your medicine is in the form of a film coated tablet. It contains Famotidine, which belongs to a group of medicines called histamine (H₂) antagonists or anti-ulcer drugs. These anti-ulcer drugs control the secretion of gastric acid in the stomach. Famotidine can prevent this acid secretion. Famotidine can be used for the following conditions:

- To help treat non-cancerous gastric (stomach) ulcers and duodenal ulcers
- To help prevent relapse of duodenal ulcers
- 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 foodpipe) and the symptoms of an inflamed foodpipe (oesophagitis)

2. BEFORE YOU TAKE FAMOTIDINE TABLETS

Do not take this medicine and tell your doctor if:

- you have taken Famotidine or a similar medicine before and suffered an allergic or unpleasant reaction
- you are allergic to any of the tablet ingredients

- you are breastfeeding.

You must tell your doctor before taking Famotidine Tablets if:

- you are pregnant or intend to become pregnant
- you have kidney problems
- you are already taking any of the following medicines:
 - Antifungal medicine eg. Itraconazole, Ketoconazole; take 2 hours before Famotidine dose
 - Probenecid, to treat gout - antacids; take Famotidine dose one to two hours before antacid
 - Sucralfate; do not take dose within two hours of Famotidine dose
 - Atazanavir, used in the treatment of HIV.

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.

Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose- galactose malabsorption

Pregnancy

If you are pregnant or planning to become pregnant, talk to your doctor first before taking this medicine. If you do get pregnant while taking Famotidine tablets you must tell the doctor straightaway.

Breast Feeding

Famotidine can pass into breast milk. Talk to your doctor before taking if you are breast-feeding or planning to breast feed

Driving and operating machines

Do not drive or operate machines if you feel dizzy or get a headache while taking Famotidine tablets.

3. HOW TO TAKE FAMOTIDINE TABLETS

Famotidine Tablets can be taken before or after food.

ADULTS (including the elderly)

Duodenal or non-cancerous stomach ulcers - The usual dose is 40 mg of Famotidine taken at bedtime. In some cases treatment may last for up to 8 weeks.

To prevent relapse of duodenal ulcers - The usual dose is 20 mg of Famotidine at bedtime.

To treat Zollinger-Ellison Syndrome - The usual starting dose is 20 mg of Famotidine four times a day. 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 the symptoms of acid reflux - The usual dose is 20 mg of Famotidine twice daily. Treatment usually lasts for 6 weeks, but if necessary, for 12 weeks.

To treat the symptoms of oesophagitis (inflammation of the foodpipe) - The usual dose is 40 mg of Famotidine twice daily. Treatment usually lasts for 6 weeks, but if necessary, for 12 weeks. If you suffer from kidney disease, your doctor will prescribe a lower dose of Famotidine.

CHILDREN Famotidine Tablets should not be given to children.

If you forget to take your dose of Famotidine Tablets unless it is almost time for your next dose, take it as soon as you remember. Otherwise, if you miss a dose do not double the next dose, just carry on as before. If you take too much of your medicine contact your doctor immediately.

4. POSSIBLE SIDE EFFECTS

Famotidine is generally well tolerated, but like all medicines, can cause unwanted effects in some patients. The most common effects, affecting less than 1 in 10 people, are constipation, diarrhoea headache and feeling dizzy.

STOP taking Famotidine and seek medical attention immediately if you notice any of the following:

- Allergic reactions including rash, itching or hives , shortness of breath, wheezing or trouble breathing, and swelling of the face, hands, feet, mouth, throat or eyes.
- yellowing of the skin or whites of the eyes, dark urine, pale stool; which may be signs of liver problems..
- A severe blistering rash in which the surface layers of the skin peel.(e.g. Stevens- Johnson syndrome or condition known as Toxic Epidermal Necrolysis(TEN)
- Also fever with sore throat or mouth ulcers, unusual bruising or bleeding of the skin, severe skin reactions, including severe blistering of the lips eyes and mouth, tightness in the chest, shortness of breath and a cough, a lung infection (pneumonia) which may be severe, muscle cramps, joint pain.

Very rarely, patients given this type of medicine by injection, have experienced an irregular heart beat.

Uncommon side effects, affecting less than 1 in 100 people, include skin rash, dry mouth, feeling unusually tired or weak, feeling or being sick, stomach upset, loss of appetite, changes in taste, wind, loss of weight and feeling bloated.

Rare effect, seen in less than 1 in 1000 people include swollen breasts in men - but it is not certain this effect is caused by Famotidine.

Very rare effects, seen in less than 1 in 10,000 people, include depression, confusion, feeling disorientated, hallucinations, feeling anxious or agitated. Impotence or loss of libido, tingling or numbness in the fingers and toes, fits, difficulty sleeping, drowsiness, a change in blood liver enzymes or suffering from hair loss

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on safety of this medicine.

5. HOW TO STORE FAMOTIDINE TABLETS

Keep Famotidine Tablets out of the reach and sight of children.

- Do not store above 25°C. Store in the original package.
- Do not take this medicine after the expiry date shown on the label.
- On the label you will find the letters 'Exp' followed by some numbers. These numbers are the date when the medicine is no longer fit for use.
- Do not use this medicine after this date.

Date of leaflet revision: March 2014