Package leaflet: Information for the user

Famotidin STADA 20 mg film -coated tablet
Famotidin STADA 40 mg film-coated tablet

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 Famotidin STADA is and what it is used for

Famotidin STADA works by reducing the amount of acid produced in the stomach. It is used to treat certain conditions caused by too much acid produced in the stomach. It is a gastrointestinal medicine that belongs to a group of medicine called Histamine H_2-receptor antagonists.

Famotidin STADA is used for:
treatment of
- symptoms of reflux disease (mild reflux oesophagitis), such as heartburn (Famotidin STADA 20 mg)
- mild to moderate inflammation of the oesophagus (food pipe) (Famotidin STADA 40 mg)
- benign gastric ulcer
- duodenal ulcer
- prevention of recurrent duodenal ulcers (only with Famotidin STADA 20 mg)
- treatment of Zollinger-Ellison-Syndrome. This is a condition caused by abnormal production of the hormone gastrin that causes an overproduction of stomach acid.

2. What you need to know before you take Famotidin STADA

DO NOT take Famotidin STADA
- if you are allergic to the famotidine or any of the other ingredients of this medicine (listed in section 6). If symptoms of hypersensitivity develop, Famotidin STADA should be discontinued.
- Children should not be treated with Famotidin STADA.

Warnings and precautions
Talk to your doctor or pharmacist before taking Famotidin STADA.

- **Tell your doctor immediately** if you notice any of the following symptoms:
  - an unintentional loss of weight
  - repeated vomiting
  - difficulty in swallowing
  - vomiting blood
  - you look pale and feel weak (anaemia)
  - you notice blood in your stools

  Your doctor may decide that you need some tests to rule out malignant disease because famotidine also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.
- If you are taking atazanavir for HIV infection (see 'Other medicines and Famotidin STADA' below).
- if you suffer from duodenal ulcers and benign gastric ulcers your doctor may decide that these have been caused by a bacterial infection with H.pylori. If this is the case you should undergo a special therapy under direction by the doctor to eliminate these bacteria.
- if you suffer from kidney (renal) impairment. Your doctor may prescribe you a lower dose of Famotidin STADA (see 3. “How to take Famotidin STADA”).
- and do not use Famotidin STADA if you suffer from minor gastrointestinal complaints. Please ask your doctor.

Other medicines and Famotidin STADA
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Please contact your doctor if you take any of the medicines mentioned below:

<u>You should not take Famotidin STADA</u>
- if you take the substance probenecid (a medicine to treat gout) at the same time, because probenecid can delay the elimination of famotidine.
- in combination with atazanavir, ritonavir and tenofovir (medicines used to treat HIV infection)

<u>The effect of Famotidin STADA can be reduced by:</u>
- medicines to neutralize the stomach acid (antacids). As the effect of Famotidin STADA will be reduced, you should take Famotidin STADA at least 1-2 hours before taking an antacid.
- sucralfate (medicine to treat ulcers). As a rule you should not take sucralfate within 2 hours of Famotidin STADA.

<u>Famotidin STADA may reduce the effect of:</u>
- ketoconazole or itraconazole (medicines to treat fungal infections). You should take ketoconazole 2 hours before taking Famotidin STADA.
- Atazanavir with ritonavir (medicines taken for HIV infection). Please ask your doctor.

Famotidin STADA with food and drink
Famotidin STADA can be taken with or without food.

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 or pharmacist for advice before taking this medicine.

<u>Pregnancy</u>
If you are pregnant Famotidin STADA should only be prescribed to you if your doctor thinks it is clearly necessary.

Breast-feeding
If you take Famotidin STADA you should refrain from breast-feeding. Famotidin STADA is excreted in breast milk and there is a possibility of it affecting the infant's gastric acid secretion.

Driving and using machines
It is not known whether Famotidin STADA affects the ability to drive or to use machines. Do not drive or operate machines until you are sure that your ability is not affected.

3. How to take Famotidin STADA

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

Method of administration:
Famotidin STADA should be swallowed whole with some liquid. It does not need to be taken at mealtimes.

The recommended dose depends on the severity of your disease and the dosage of previous medications. Your doctor will decide how much you should take.

Recommended doses are given below:

Treatment of symptoms of reflux disease (e.g. heartburn)

20 mg of famotidine twice a day.

Treatment of mild to moderate inflammation of the oesophagus (food pipe)
40 mg of famotidine twice a day.

Benign gastric ulcers and duodenal ulcers
40 mg of famotidine before going to sleep.

The therapy should last for 4 to 8 weeks. However, this period may be shortened if your doctor finds that the ulcer has healed (e.g. by an endoscopic examination). If the examination does not show that the ulcer has healed then treatment should be continued for another 4 weeks.

Prevention of recurrent duodenal ulcers
20 mg of famotidine in the evening.

The recommended maintenance dose of 20mg has been continued effectively in clinical studies of 12 months duration.

Zollinger-Ellison syndrome
Providing there has not been previous therapy, the treatment starts with 20 mg of famotidine every 6 hours.

Depending on the acid secretion and your clinical response, your doctor may increase the dose as treatment continues until the desired acid levels have been reached. If treatment with a daily dosage of up to 800 mg doesn't work, your doctor may consider an alternative treatment to regulate acid secretion.

If you have previously undergone a treatment with similar medicines (e.g. other Histamine H_2 receptor antagonists) it is possible to start the treatment with Famotidin STADA at a higher dosage than the initial dosage that is usually recommended. Ask your doctor about the right

dosage.

Treatment should be continued for as long as necessary.

Patients with impaired kidney (renal) function
If you suffer from impaired renal function your doctor may reduce the daily dose to 50%. Dialysis patients should also take dosages that are reduced to 50%. Famotidin STADA should be administered at the end of dialysis or thereafter since some of the active ingredient is removed via dialysis.

If you take more Famotidin STADA than you should
Contact your doctor or the nearest hospital immediately. Your doctor will make efforts to inhibit absorption and relieve symptoms. Up to now there are no reports of overdosing with the active ingredient famotidine.

If you forget to take Famotidin STADA
If you forget to take a dose, take one as soon as you remember and continue as before. Do not take a double dose to make up for a forgotten dose. If you are concerned about missing your dose ask your doctor for advice.

If you stop taking Famotidin STADA
Talk to your doctor if you wish to stop taking Famotidin STADA.

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 the medicine and contact your doctor immediately if you get serious allergic/hypersensitivity reactions which causes difficulty in breathing or dizziness (anaphylaxis), swelling of the face or throat (angioneurotic oedema), difficulty in breathing or wheezing (bronchospasm).

The following side effects have been reported:

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

Uncommon side-effects (may affect up to 1 in 100 people):
- dry mouth
- nausea, vomiting
- gastrointestinal complaints
- wind (flatulence)
- loss of appetite
- rash, itching (pruritus)
- tiredness (fatigue)

Rare side-effects (may affect up to 1 in 1,000 people):
- serious allergic/hypersensitivity reactions which causes difficulty in breathing or dizziness (anaphylaxis), swelling of the face or throat (angioneurotic oedema), difficulty in breathing

or wheezing (bronchospasm)
- yellowing of the skin or the whites of the eyes caused by blockade of bile flow (jaundice caused by intrahepatic cholestasis)
- hives (urticaria)
- joint pain (arthralgia)
- increase in laboratory values (transaminases, gamma GT, alkaline phosphatase, bilirubin)

Very rare side-effects (may affect up to 1 in 10,000 people):
- changes in the blood: a fall in the number of all types of blood cells (pancytopenia) or a fall in the number white blood cells (leukopenia, agranulocytosis) or blood platelets (thrombocytopenia), which can cause e.g. weakness, fatigue, sudden fever, sore throat, bruising or nose bleed.
- reversible psychological disturbances (e.g. hallucinations, disorientation, confusion, anxiety, agitation, depression)
- tingling or numbness in the hand or feet (paraesthesia)
- drowsiness
- sleeplessness
- epileptic seizures (grand mal)
- hair loss
- severe skin reactions (e.g. toxic epidermal necrolysis)
- muscle cramps
- impotence, reduced libido
- feelings of tightness in the chest

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Famotidin STADA

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 blister and outer packaging after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Famotidin STADA contains
The active substance is famotidine.

Famotidin STADA 20 mg film-coated tablets:
1 film-coated tablet contains 20 mg of famotidine.

Famotidin STADA 40 mg film-coated tablets:
1 film-coated tablet contains 40 mg of famotidine.

The other ingredients are:
Tablet core: Microcrystalline cellulose, maize starch, pre-gelatinised maize starch, povidone, talc, magnesium stearate.

Tablet coat: Hypromellose, talc, titanium dioxide (E171), propylene glycol.

What Famotidin STADA looks like and contents of the pack
Famotidin STADA 20 mg film-coated tablets:
Round, biconvex, white film-coated tablets, engraved “20” on one side.

Famotidin STADA 40 mg film-coated tablets:
Round, biconvex, white film-coated tablets, engraved “40” on one side.

The film-coated tablets are packed in PVC/PVDC-aluminium blister packs.
10, 15, 20, 28, 30, 50, 56, 60, 90, 100, 250, 500, 1000 film-coated tablets
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
STADA Arzneimittel AG
Stadastraße 2 - 18
61118 Bad Vilbel
Germany

Manufacturer
Centrafarm Services B.V.
Nieuwe Donk 9,
4870 AC Etten-Leur
The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Famotidin "Stada" 20 mg/40 mg – Filmtabletten
Belgium	Famotidine EG 20 mg/40 mg filmomhulde tabletten
France	Famotidine EG
Germany	Famotidin Stada 20 mg/40 mg
Ireland	Famulco
Italy	Famotidina EG 20 mg/40 mg
Luxembourg	Famotidine EG
Netherlands	Famotidine CF
Sweden	Famotidin Stada 20 mg/40 mg, filmdragerad tablett

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