Package leaflet: information for the user

famotidina cinfa 20 mg film-coated tablets

Please read this leaflet carefully before you start taking this medicine because it contains important information for you.

--Keep this leaflet, as you may need to read it again.
--If you have any questions, ask your doctor or pharmacist.
--This medicine has been prescribed for you. Do not pass it on to others even if they have the same symptoms, as it may harm them.
-- If you get any side effects, talk to your doctor or pharmacist, even for side effects not listed in this leaflet.

In this leaflet:

1. What famotidina cinfa is used for

famotidina cinfa is used to treat diseases which are associated with the acid produced by the stomach.
famotidina cinfa 20mg is indicated for:

- Treatment and relapses of duodenal and gastric ulcers.
- Treatment of Zollinger-Ellison syndrome.
- Treatment of heartburn and acid reflux.
- Treatment of inflammation of the oesophagus (reflux oesophagitis).
- Prevention of gastroesophageal reflux (irritation and inflammation of the oesophagus).

1. What you need to know before taking famotidina cinfa

Do not take famotidina cinfa:

- If you are allergic to famotidine or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to other H2 receptor antagonists.

If you are not sure whether you should take famotidina cinfa, ask your doctor.

Warnings and precautions:
Before starting treatment, your doctor must rule out the existence of other more serious diseases. If your doctor has not ruled out the existence of gastric cancer before starting treatment with famotidine. Relief of the symptoms of gastric ulcer during treatment does not rule out the presence of a malignant ulcer.

Talk to your doctor or pharmacist before taking famotidine in the following cases:

- If you have moderate to severe kidney or liver disease. Adverse reactions on the CNS have been reported in patients with moderate to severe renal impairment. Your doctor will tell

you the lowest frequency of administration or the lowest dose you should take.

- If you are an elderly person, because you may have renal impairment.

If you have been taking famotidine for some time, your doctor will probably ask you to have regular check-ups. When you visit your doctor, you should inform him/her about any new or unusual symptoms or circumstances.

Children:
The safety and efficacy of this medicine has not been evaluated in children.

Elderly patients:
Your doctor will choose the right dose for you and it may be necessary to monitor your kidney function. Patients over 65 years of age only require dose adjustment in cases of moderate to severe renal impairment.

Other medicines and famotidina cinfa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
-calcium carbonate, when used to treat high blood phosphorus levels (hyperphosphataemia) in dialysis patients.

famotidina cinfa with food and drink
The absorption of famotidine is not affected when given with meals.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before using any medicine.

Pregnancy:
Treatment with famotidine is not recommended during pregnancy. 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.

Breast-feeding:
Famotidine is excreted in human milk. Nursing mothers should discontinue treatment with famotidine or stop breast-feeding.

Driving and using machines
Although related side effects are not expected, if you feel dizzy, do not drive or use dangerous machinery.

Interaction with laboratory tests
If you are having a diagnostic test, tell you doctor you are using this medicine, since it could alter the results.

This medicine contains sodium.
This medicine contains less than 1 mmol (23 mg) of sodium per tablet; that is, essentially "sodium-free".

2. How to take famotidina cinfa

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

Your doctor will prescribe the right dose for you and tell you how long to take it, depending on your condition. Only take the amount the doctor prescribes for you.

Treatment of duodenal ulcer:
The normal dose is 2 tablets (40 mg of famotidine) in the evening. One tablet (20 mg of famotidine) can also be given every 12 hours. Treatment should be continued for 4 to 8 weeks.

Treatment of benign gastric ulcer:
The normal dose is 2 tablets (40 mg of famotidine) in the evening. Treatment should be continued for 4 to 8 weeks.

Maintenance treatment of duodenal or gastric ulcer
The normal dose to prevent peptic ulcers from recurring is 1 tablet (20 mg of famotidine) in the evening. Your doctor will tell you how long you should take this medicine.

Treatment of gastroesophageal reflux disease (GERD)
The normal dose is 1 tablet (20 mg of famotidine) twice a day. If there is no improvement after 4-8 weeks, talk to your doctor.

Healing of ulcer associated with gastroesophageal reflux
The recommended dose is 2 tablets (40 mg of famotidine) twice a day. If there is no improvement after 4-8 weeks, talk to your doctor.

Zollinger-Ellison syndrome
Treatment will normally begin with a dose of 1 tablet (20 mg of famotidine) every 6 hours. The doctor will then adjust the dose according to each patient's needs.

Dose adjustment in patients with moderate to severe renal impairment
The doctor will decide whether it is necessary to adjust the dose, either by halving it or by increasing the time between doses to 36-48 hours, depending on your response.

Elderly patients only require dose adjustment in cases of renal impairment.

If you consider that the effect of famotidina cinfa is too strong or too weak, tell your doctor or pharmacist.

Method of administration
The tablet should be swallowed whole with a little water. Your doctor will tell you how many tablets a day you should take and for how long.

If you take more famotidina cinfa than you should
Adverse reactions in cases of overdose are similar to the adverse reactions seen in normal clinical experience.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, indicating the medicine and the amount taken.

If you forget to take famotidina cinfa
If you forget to take a dose, take it as soon as possible unless it is almost time to take the next dose. In this case, do not take the forgotten dose and take the following tablets as normal. Do

not take a double dose to make up for a forgotten dose.

If you stop taking famotidina cinfa
You should not stop treatment suddenly or early, even though your symptoms may have improved. Treatment should always be stopped gradually and according to your doctor's instructions to avoid relapses.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

3. Possible side effects

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

Common side effects (may affect up to 1 in 10 people)
- Nervous system disorders: headache, dizziness.
- Gastrointestinal disorders: constipation, diarrhoea.

Uncommon side effects (may affect up to 1 in 100 people)
- General disorders and administration site conditions: persistent lack of appetite, fatigue.
- Gastrointestinal disorders: nausea, vomiting, discomfort or bloating (swelling of the abdomen), dry mouth, excessive intestinal gas.
- Skin and subcutaneous tissue disorders: skin rash, pruritus (itching or irritation of the skin).
- Musculoskeletal and connective tissue disorders: joint pain, muscle cramps.
- Psychiatric disorders: reversible mental disorders including depression, anxiety disorders, agitation, confusion and hallucinations.

Rare side effects (may affect up to 1 in 1,000 people)
- General disorders and administration site conditions: anaphylaxis unusual or exaggerated allergic reaction), angioneurotic oedema (serious allergic reaction with inflammation of the face, lips, tongue, throat and even limbs with difficulty swallowing or breathing).
- Skin and subcutaneous tissue disorders: Urticaria (skin wheals).
- Hepatobiliary disorders: cholestatic jaundice (yellow colouring of the skin).

Very rare side effects (may affect up to 1 in 10,000 people)
- Skin and subcutaneous tissue disorders: toxic epidermal necrolysis (peeling of the skin) and hair loss.
- Investigations: liver enzyme abnormalities.

If you get any side effects, talk to your doctor or pharmacist, even if it is a possible side effect not listed in this leaflet.

4. How to store famotidina cinfa

Do not store above 25°C.
Keep this medicine out of the sight and reach of children.
Do not use famotidina cinfa after the expiry date on the carton after "EXP". The expiry date is the last day of that month.

Medicines should not be disposed of via wastewater or household waste. If in doubt, ask your pharmacist how to dispose of medicines you no longer require. This helps to protect the environment.

5. Contents of the pack and other information

famotidina cinfa composition

--The active ingredient is famotidine. Each tablet contains 20mg of famotidine.
--The other ingredients are:
--Tablet core: croscarmellose sodium, talc, microcrystalline cellulose and magnesium stearate.
--Tablet coating: yellow iron oxide, red iron oxide (E172), Opadry Y-1-7000 (titanium dioxide (E171)/ hypromellose/polyethylene glycol 400).

Contents of the pack

famotidina cinfa comes in blister packs of 28 film-coated tablets.

Marketing authorisation holder and manufacturer
Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10 Polígono Industrial Areta
31620 Huarte (Navarre) – Spain

Distributor
Reich Pharm Limited
Unit 3001, 30/F, Citicorp Centre,
18 Whitfield Road,
Hong Kong
Tel.: 2470 1927
Fax.: 2470 3448
HK Reg. No. 51630

This leaflet was last revised in: September 2018

Package leaflet: information for the user

famotidina cinfa 40 mg film-coated tablets

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- If you get any side effects, talk to your doctor or pharmacist, even for side effects not listed in this leaflet.

In this leaflet:

1. What famotidina cinfa is used for

famotidina cinfa is a medicine belonging to the group of drugs called H_2 receptor antagonists or H_2 blockers. These medicines are used to treat diseases associated with the acid produced by the stomach.

famotidina cinfa 40 mg is indicated in:
- Treatment and relapses of duodenal and gastric ulcers.
- Treatment of Zollinger-Ellison syndrome.
- Treatment of heartburn and acid reflux.
- Treatment of inflammation of the oesophagus (reflux oesophagitis).
- Prevention of gastroesophageal reflux (irritation and inflammation of the oesophagus).

1. What you need to know before taking famotidina cinfa

Do not take famotidina cinfa:
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- If you are allergic to other H2 receptor antagonists.

If you are not sure whether you should take famotidina cinfa, ask your doctor.

Warnings and precautions:
Before starting treatment, your doctor must rule out the existence of other more serious diseases. If your doctor has not ruled out the existence of gastric cancer before starting treatment with famotidine. Relief of the symptoms of gastric ulcer during treatment does not rule out the presence of a malignant ulcer.

Talk to your doctor or pharmacist before taking famotidine in the following cases:

- If you have moderate to severe kidney or liver disease. Adverse reactions on the CNS have been reported in patients with moderate to severe renal impairment. Your doctor will tell you the lowest frequency of administration or the lowest dose you should take.
- If you are an elderly person, because you may have renal impairment.

If you have been taking famotidine for some time, your doctor will probably ask you to have regular check-ups. When you visit your doctor, you should inform him/her about any new or unusual symptoms or circumstances.

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The safety and efficacy of this medicine has not been evaluated in children.

Elderly patients:
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Other medicines and famotidina cinfa
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
-calcium carbonate, when used to treat high blood phosphorus levels (hyperphosphataemia) in dialysis patients.

famotidina cinfa with food and drink
The absorption of famotidine is not affected when given with meals.

Pregnancy and breast-feeding
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Pregnancy:
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Breast-feeding:
Famotidine is excreted in human milk. Nursing mothers should discontinue treatment with famotidine or stop breast-feeding.

Driving and using machines
Although related side effects are not expected, if you feel dizzy, do not drive or use dangerous machinery.

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If you are having a diagnostic test, tell you doctor you are using this medicine, since it could alter the results.

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Treatment of duodenal ulcer:
The normal dose is 1 tablet (40 mg of famotidine) in the evening. Half a tablet (20 mg) can also be given every 12 hours. Treatment should be continued for 4 to 8 weeks.

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Maintenance treatment of duodenal or gastric ulcer
The normal dose to prevent peptic ulcers from recurring is half a tablet (20 mg of famotidine) in the evening. Your doctor will tell you how long you should take this medicine.

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The recommended dose is 1 tablet (40 mg of famotidine) twice a day. If there is no improvement after 4-8 weeks, talk to your doctor.

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If you consider that the effect of famotidina cinfa is too strong or too weak, tell your doctor or pharmacist.

Method of administration
The tablet should be swallowed whole with a little water. Your doctor will tell you how many tablets a day you should take and for how long.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more famotidina cinfa than you should
Adverse reactions in cases of overdose are similar to the adverse reactions seen in normal clinical experience.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately or call the Toxicology Information Service, telephone +34 91 562 04 20, specifying the medicine and the amount ingested.

If you forget to take famotidina cinfa

If you forget to take a dose, take it as soon as possible unless it is almost time to take the next dose. In this case, do not take the forgotten dose and take the following tablets as normal. Do not take a double dose to make up for a forgotten dose.

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Marketing authorisation holder and manufacturer

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10 Polígono Industrial Areta
31620 Huarte (Navarre) – Spain

Distributor

Reich Pharm Limited
Unit 3001, 30/F, Citicorp Centre,
18 Whitfield Road,
Hong Kong
Tel.: 2470 1059
Fax.: 2470 3448
HK.Reg.No. 51631

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