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 you, 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:

PR031759E16-23003

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 which are associated with the acid produced by the stomach.
famotidina cinfa 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).

2. 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 famotidine, 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 famotidina cinfa 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.
- 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).

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".

3. 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 recommended 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 recommended 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 recommended dose to prevent peptic ulcers from recurring is 1 tablet (20 mg of famotidine) administered in the evening. Your doctor will tell you how long you should take this medicine.

Treatment of gastroesophageal reflux disease (GERD)
The recommended 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 famotidine 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.

4. 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.

5. 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.

6. Contents of the pack and other information

famotidina cinfa composition
- The active ingredient is famotidine. Each film-coated tablet contains 20 mg 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
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HK Reg. No. 51630

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cinfa

莎華 -「洛胃能」20 毫克

此說明書含有重要資訊, 使用此藥物前請細心閱讀此說明書全部內容。
- 請保留此說明書，以便可以再次翻閱。
- 如有任何問題，請向您的醫生或藥劑師查詢。
- 此藥只處方給您，請勿給其他人使用，即使對方病徵跟您相似也可能造成傷害。
- 如有任何副作用，請咨詢醫生或藥劑師，此包括任何未有在此說明書列出的任何可能的副作用。

這張說明書內包含甚麼資料？

1. 莎華 -「洛胃能」用於甚麼情況

莎華 -「洛胃能」是一種屬於 H2 受體對抗劑或 H2 受體阻抗劑的藥物。 這些藥物用於治療與胃酸有關的疾病。

莎華 -「洛胃能」適用於以下情況：
十二指腸潰瘍和胃潰瘍的治療和復發。
- 治療佐格林-埃利森綜合症。
- 治療胃灼熱和胃酸反流。
- 治療食道炎症（反流性食管炎）。
- 預防胃食管反流（食道刺激和炎症）。

2. 使用莎華 -「洛胃能」前您需要留意甚麼？

請勿使用莎華 -「洛胃能」假如您：
- 對莎華 -「洛胃能」主要成份法莫替丁 (Famotidine) 或其他任何成份過敏(請參閱第 6 部)
- 對其他 H2 受體對抗劑過敏

如果您不確定是否應該服用法莫替丁 (Famotidine)，請諮詢您的醫生。

警告和預防措施
在開始治療之前，您的醫生必須排除其他更嚴重疾病的存在。 如果您的醫生在開始用法莫替丁治療之前必須排除胃癌的存在。 因爲在治療過程中緩解胃潰瘍症狀可能會延誤這些疾病的診斷。

在下列情況下服用法莫替丁 (Famotidine) 之前，請諮詢您的醫生或藥劑師：
- 如果您患有中度至嚴重的腎臟或肝臟疾病。 根據報告，中度至嚴重的腎功能不全患者對中樞神經系統有不良反應。 您的醫生會指示您應該服用較小次數或較低劑量。
- 如果您是老年人，因爲您可能有腎衰竭的情況。

兒童：
此藥的安全性和有效性尚未在兒童中進行評估。

老年患者：
您的醫生會爲您選擇合適的劑量以及可能需要監測您的腎功能。 65 歲以上的患者僅需要在中度至嚴重腎功能損害的情況下調整劑量。

其他藥物和莎華 -「洛胃能」
請告訴您的醫生或藥劑師，如您正使用、最近使用或打算使用其他藥物(包括無需處方的藥物)。
- 碳酸鈣，用於治療透析患者的高血磷水平（高磷酸鹽血症）。
- 法莫替丁可能會降低泊沙康唑口服混懸液（一種用於預防和治療某些真菌感染的飲用藥物）的作用。
- 法莫替丁可能會降低達沙替尼、厄洛替尼、吉非替尼、帕唑帕尼（用於治療癌症的藥物）的效果。

飲食方面
法莫替丁(Famotidine) 在用餐時不會影響其吸收狀況。

懷孕及哺乳期
使用本藥前請先向您的醫生或藥劑師查詢。

懷孕期
懷孕期間不建議使用法莫替丁(Famotidine) 治療。 如果您懷孕或哺乳，認爲您可能懷孕或計劃生孩子，請在服用此藥前諮詢醫生或藥劑師。

哺乳期
法莫替丁(Famotidine) 會經由母乳排出。哺乳期婦女應立即停止使用法莫替丁 (Famotidine) 或停止餵哺母乳。

駕駛及操作機器
雖然沒有預期有任何影響，假如您感覺頭暈，不應駕駛或操作機器。

與實驗室測試的互動
如果您正在進行診斷測試，請告訴醫生您正在使用此藥，因爲它可能會改變結果。

此藥含有鈉
此藥每片含有少於 1 毫摩爾（23 毫克）的鈉; 也就是說，基本上是“無鈉”。

3. 如何使用莎華 -「洛胃能」

請遵照醫生的指示使用莎華 -「洛胃能」。如有疑問，請諮詢您的醫生或藥劑師。並請謹記按時服藥。

您的醫生會按照您的病情開出合適的劑量，並根據您的情況告訴您服用多長時間，請只服用醫生規定的劑量。

治療十二指腸潰瘍
建議的服用劑量是每天晚上服用 2 粒(法莫替丁 40 毫克)。亦可以每 12 小時服用一次 1 粒(法莫替丁 20 毫克)。療程應持續 4-8 星期。

治療胃潰瘍
建議的服用劑量是每天晚上服用 2 粒(法莫替丁40 毫克)。療程應持續 4-8 星期。

保養治療十二指腸潰瘍或胃潰瘍
預防消化性潰瘍復發的建議劑量是晚上服用 1 粒(（法莫替丁20 毫克）。 您的醫生會告訴您應該服用這種藥多長時間。

治療反流性食道炎 (GERD)
建議劑量是每天兩次，每次 1 粒（20 毫克法莫替丁）。如果 4-8 週後沒有改善，請諮詢您的醫生。

治療由於胃食道反流引起的食道炎
建議使用劑量爲每日 2 次每次 2 粒（40 毫克法莫替丁），持續 4-8 星期。如果情況沒有改善，請諮詢您的醫生。

佐格林-埃利森綜合症
治療通常以每 6 小時 1 粒莎華（20 毫克法莫替丁）開始。醫生會根據每個病人的需要再調整劑量。

中度或嚴重腎功能受損的患者
醫生將根據您的反應決定是否有必要通過減半或將劑量間隔增加到 36-48 小時來調整劑量。

長者只會在有腎臟損傷的情況下才需要調整劑量。

如果您覺得法莫替丁的效果太強或太弱，請告訴您的醫生或藥劑師。

使用方法
用開水送服。按醫生指示服用每天的攝取量，次數及療程時間。

如果您整個吞嚥困難，藥片上的分線能幫助您把藥片分開兩邊服用。

如使用莎華 -「洛胃能」多於您應使用份量
過量服用的不良反應與正常臨床經驗中的不良反應相似。

如果服用過量或意外，請立即通知您的醫生或藥劑師，說明藥物和服用量。

假如您忘記使用莎華 -「洛胃能」
如果您忘記服用一次，請盡快服用，除非幾乎是接受下一次劑量的時間。 在這種情況下，不要服用被遺忘的劑量，並照常服用以下藥片。 不要服用雙倍劑量來彌補被遺忘的劑量。

假如您停止使用莎華 -「洛胃能」
即使您的症狀可能有所改善，您也不應該突然或提停止治療。 應始終根據醫生的指示逐步停止治療，以避免復發。

如果您對使用此藥有任何疑問，請諮詢您的醫生或藥劑師。

4. 可能的副作用

像其他藥物一樣，此藥物可能會引起副作用，儘管並不是所有人都會有此情況。

常見的副作用 (每10人中有1人可能會受影響)
- 神經系統疾病：頭痛、頭暈
- 胃腸功能紊亂：便秘、腹瀉

不常見的副作用 (每100人中有1人可能會受影響)
- 一般疾病：食慾不振、乏力
- 胃腸道疾病：噁心、嘔吐、腹部不適或脹（腹脹）、口乾
- 皮膚和皮下組織疾病：皮疹，痕癢（皮膚痕癢或刺痛）
- 肌肉骨骼和結締組織疾病：關節疼痛、肌肉痙攣
- 精神障礙：可逆性精神障礙，包括抑鬱症、焦慮症、興奮、混亂和幻覺。
- 多餘的腸氣

罕見的副作用 (每1,000人中有1人可能會受影響)
- 一般疾病：過敏性反應（異常或過敏反應），血管水腫（嚴重過敏反應引致臉部、嘴唇、舌頭、喉嚨腫脹，甚至吞嚥困難或呼吸困難）。
- 皮膚和皮下組織疾病：蕁麻疹（皮膚腫痛）
- 肝膽疾病：膽汁淤積性黃疸（皮膚泛黃）

非常罕見的副作用 (每10,000人中有1人可能會受影響)
- 皮膚和皮下組織疾病：中毒性表皮溶解症（皮膚剝落）及脫髮。
- 探討中：肝酶異常

如果您出現任何副作用，請諮詢您的醫生或藥劑師，即使本說明書中未列出的可能副作用。

5. 如何貯存莎華 -「洛胃能」

請貯存於攝氏 25 度下。
請將藥物存放於兒童不能觸及和視線範圍以外。

在莎華 -「洛胃能」紙盒上註明的有效期後（月/年）切勿使用，有效期所指的是每個月最後一日。

請勿丟棄任何藥物於污水及家居垃圾中，請向您的藥劑師查詢如何棄置不再使用的藥物，這項措施有助保護環境。

6. 包裝及其他資料

莎華 -「洛胃能」包含什麼：

主要成份是法莫替丁(famotidine)。每粒薄膜衣片含有 20 毫克法莫替丁(famotidine)。

其他成份：
藥片主體：croscarmellose sodium, talc, microcrystalline cellulose, magnesium stearate。

藥片外層：yellow iron oxide, red iron oxide (E172), Opadry Y-1-7000 (titanium dioxide (E171)/ hypromellose/polyrthylene glycol 400)。

莎華 -「洛胃能」的包裝
每盒裝有 28 粒薄膜衣片

製造商及營銷持有人
Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta
31620 Huarte (Navarre) - Spain

代理商
漢生醫藥有限公司
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HK Reg. No. HK-51630

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cinfa