GASTRODOMINA

Famotidine

TABLETS

COMPOSITION per tablet:	Gastrodomina 20 mg	Gastrodomina 40 mg
Famotidine	20 mg	40 mg
Excipient (containing lactose), s.q.		

Famotidine is a prolonged-action H-2 antagonist. Its onset is rapid and it has a high degree of specificity for H-2 receptors.

INDICATIONS Oral famotidine is indicated in: duodenal ulcer, benign gastric ulcer, hypersecretory syndromes such as Zollinger Ellison syndrome and in maintenance therapy for reducing recurrences of duodenal ulcer.

DOSAGE: Tablets

Duodenal ulcer:
The recommended dose of famotidine is one 40 mg tablet daily before going to sleep. A 20 mg tablet can also be taken every 12 hours. The treatment should be continued for 4 to 8 weeks although this period may be shortened if the endoscopy shows that the ulcer has healed. In most duodenal ulcer cases, healing occurs after 4 weeks of treatment. If the ulcer does not heal during this period, treatment should be continued for a further four weeks.
Maintenance therapy: In order to reduce recurrences of duodenal ulcer, it is recommended to continue daily treatment with a 20 mg dose before going to sleep. It should be pointed out, however, that no controlled studies have been performed for periods exceeding one year.
Benign gastric ulcer:
The recommended dose is 40 mg daily before going to sleep. The treatment should be continued for 4 to 8 weeks although this period may be shortened if the endoscopy shows that the ulcer has healed.
Zollinger Ellison' syndrome:
In patients that have not received any previous antisecretory treatment, therapy should be started at a dose of 20 mg every 6 hours. This dose should be adjusted to each patient's individual needs and should be continued for as long as may be clinically necessary. Doses of up to 480 mg daily have been used for one year without observing any significant adverse reactions or tachyphylaxis. In patients that have received previous antisecretory treatment, the starting dose of famotidine should be higher than that recommended for cases in the early stages, adjusting it to the seriousness of the clinical picture and the dose of H-2 antagonist previously used.

WARNING This speciality contains lactose. Cases of intolerance to this component have been reported in children and adolescents causing diarrhoeas complicated with intestinal infection, dehydration, and acidose. If these symptoms arise treatment should be immediately discontinued.

CONTRAINDICATIONS There are no known contraindications to the use of famotidine. If signs of hypersensitivity appear, treatment with the drug should be discontinued immediately.

PRECAUTIONS The absence of stomach cancer should be established before starting treatment with famotidine. The symptomatic relief of gastric ulcer during treatment does not rule out the presence of a malignant gastric ulcer.
Famotidine should be used with caution in patients with impaired liver or kidney function. If creatinine clearance falls to 30 ml/min or below, a reduction in the dose should be considered.
Famotidine is not recommended in pregnancy and should only be prescribed when clearly necessary. Before using famotidine in pregnant patients, the drug's potential benefits should be carefully weighed against the possible risks.
It is not known if famotidine is excreted into breast milk. Nursing mothers should discontinue use of famotidine or stop breastfeeding.
The safety or efficacy of famotidine in children has not been established.
No changes in the type of side effects or increases in the incidence of side effects were observed when famotidine was administered to elderly patients.
In any case, the treatment will be discontinued progressively and under medical supervision to prevent relapses.

INCOMPATIBILITIES None have been described.

INTERACTIONS No interactions with other drugs have been established. The studies performed show that it does not cause any significant interference with the metabolism of compounds by hepatic microsomal enzymes. In man, it is unlikely that it will interact with warfarin, propranolol, theophyllin or diazepam.

SIDE EFFECTS On rare occasions, diarrhoea, headache and tiredness have been described. Other even rarer side effects are constipation, dry mouth, nausea and vomiting, intestinal disturbances, flatulence, loss of appetite and skin eruption.
However, at present it is not possible to rule out the possibility of other adverse effects appearing of the type observed in other H-2 antagonists.

INTOXICATION AND TREATMENT No experience is available on overdoses. Doses of up to 640 mg/day have been used in patients with hypersecretory syndromes without observing any serious side effects. In the event of accidental overdosage, the usual procedures for removing the non-absorbed medicine from the gastrointestinal tract should be followed, the patient should be closely monitored and a support therapy should be given.

STORAGE CONDITIONS
Store in a cool place, protect from light.

DISPENSING
Prescription only

PRESENTATION
Gastrodomina 20 mg, pack of 20 tablets
Gastrodomina 40 mg, pack of 10 tablets

Keep medicines out of children's reach

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