SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FAMOCID (Famotidine)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

FAMOCID (Famotidine) 20MG Tablet

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Gastric ulcer, duodenal ulcer, anastomotic ulcer, bleeding of upper alimentary tract(by peptic ulcer, acute stress ulcer, hemorrhagic gastritis), reflux esophagitis, Zolloinger-Ellison syndrome.
- Improvement of gastric mucosa lesion(erosion, hemorrhage, rubor, edema) of the following diseases : acute gastritis and acute aggravated stage of chronic gastritis.

4.2 Posology and method of administration

- Gastric ulcer, duodenal ulcer, anastomotic ulcer, bleeding of upper alimentary tract(by peptic ulcer, acute stress ulcer, hemorrhagic gastritis), reflux esophagitis, Zolloinger-Ellison syndrome. : The recommended adult oral dosage is 20mg(by Famotidine) twice a day after meal(morning & night) or 40mg(by Famotidine) once a day at bedtime.

- Improvement of gastric mucosa lesion(erosion, hemorrhage, rubor, edema) of the following diseases : acute gastritis and acute aggravated stage of chronic gastritis. : The recommended adult oral dosage is 10mg(by Famotidine) twice a day after meal(morning & night) or 20mg(by Famotidine) once a day at bedtime. The dosage can be adjusted by age and severity of symptoms.

Method of administration

For oral use.

Famotidine tablets can be taken with or without food (see section 5.2).

4.3 Contraindications

Hypersensitivity to any component of these products

4.4 Special warnings and precautions for use

Special care should be taken with the following patients.

- Patients with a history of hypersensitivity to this drug
- Patients with a renal disorder
- Patients with a heart failure
- Patients with a hepatopathy
- The aged

General

Symptomatic response to therapy with FAMOTIDINE does not preclude the presence of gastric
malignancy.

Patients with Severe Renal Insufficiency

Longer intervals between doses or lower doses may need to be used in patients with severe renal insufficiency(creatinine clearance < 10 mL/min) to adjust for the longer elimination half-life of famotidine. However, currently, no drug-related toxicity has been found with high plasma concentrations of famotidine.

Pediatric Use

Safety and effectiveness in children have not been established.

Use in Elderly Patients

No dosage adjustment is required based on age. Dosage adjustment in the case of severe renal impairment may be necessary.

4.5 Interaction with other medicinal products and other forms of interaction

Coadministration of Itraconazole may reduce oral absorbtion of it.
lterations of gastric pH may affect the bioavailability of certain drugs, resulting in a decrease in the absorption of atazanavir. The absorption of ketoconazole and itraconazole could be reduced. Ketoconazole should be administered two hours before famotidine.

Probenecid inhibits the renal tubular secretion of famotidine and has been shown to cause a 50% increase in famotidine plasma concentrations. Therefore, concomitant use of probenecid and famotidine should be avoided.

Concomitant use of famotidine and antacids could reduce the famotidine absorption and lead to lower plasma levels of famotidine. Therefore, famotidine should be administered 1-2 hours before taking an antacid.

Concomitant use of sucralfate inhibits the absorption of famotidine. Therefore, sucralfate should not be administered within 2 hours of the famotidine dose.

Risk of loss of efficacy of calcium carbonate when co-administered as phosphate binder with famotidine in haemodialysis patients.

4.6 Fertility, pregnancy and lactation

Pregnancy

Reproductive studies have revealed no significant evidence of impaired fertility or harm to the fetus due to FAMOTIDINE. This drug should be used during pregnancy only if clearly needed.

Nursing Mothers

Studies performed in lactating rats have shown that famotidine is secreted into breast milk. Transient growth depression was observed in young rats suckling from mothers treated with maternotoxic doses of at least 600 times the usual human dose. Famotidine is detectable in human milk. Because of the potential for serious adverse reactions in nursing infants from FAMOTIDINE, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

→ Shock, Hypersensitivity (not more than 0.1%) : Shock, Hypersensitivity(dyspnea, angioedema, <facial edema, pharyngeal edema etc.>, urticaria etc.)

→ Panhematopenia, agranulocytosis, aplastic anemia, hemoclastic anemia(obscured frequency) : general malaise , inertia, hypodermatic or submucous bleeding, febricity etc.

→ Stevens-Johnson syndrome(mucocutaneous ocular syndrome), Lyell's syndrome(toxic epidermal necrolysis)(obscured frequency)

→ Dyshepatia, jaundice(obscured frequency) : elevations of AST or ALT, jaundice

→ Rhabdomyolysis

→ Prolonged QT Syndrome, ventricular tachycardia, (including Torsade de pointes). Ventricular fibrillation (obscured frequency)

→ Conscious disorder, convulsion(obscured frequency)

→ Epileptogenic nephritis, acute renal failure(obscured frequency)

→ Ventricular asystole

4.9 Overdose

The adverse reactions in overdose cases are similar to the adverse reactions encountered in normal clinical experience (see section 4.8).

In the event of overdose the usual measures to remove unabsorbed material from the gastrointestinal tract, clinical monitoring and supportive therapy should be employed.

Patients suffering from Zollinger-Ellison syndrome have tolerated doses of up to 800 mg/day. These patients have been treated for more than a year without the development of any significant adverse effects.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD), H_2-receptor antagonists.

Clinical efficacy and safety

In healthy volunteers, single oral doses of famotidine (5 mg to 40 mg) produced dose related inhibition of basal and pentagastrin, betazole or insulin-stimulated gastric secretion. In addition, pepsin levels were also reduced and there was a decrease in the volume of the basal gastric juice and the gastric juice secreted on stimulation. Similar inhibitory effects on gastric secretion were also noted in patients with benign gastric or duodenal ulceration.

In contrast to control subjects on cimetidine 300 mg or on placebo, inhibition of gastric secretion persisted in volunteers given a second pentagastrin challenge 5-7 hours after the initial dose of famotidine.

A single oral dose of 40 mg of famotidine, given at 9 pm was effective for more than 12 hours after administration and had some continuing effect through the breakfast meal. The duration of action of the 80 mg dose of famotidine administered at 9 pm was no longer than the 40 mg dose.

In several studies, 10 mg and 20 mg doses of famotidine increased basal serum gastrin levels, however the levels remained unchanged in others. Gastric emptying, and hepatic and portal blood flows were unaltered by famotidine. In addition, famotidine did not cause changes in endocrine function.

5.2 Pharmacokinetic properties

Absorption.

Famotidine is rapidly absorbed and takes effect within an hour of oral administration, reaching dose-related peak plasma concentration within 1-3 hours. Oral bioavailability is not affected by the presence of food in the stomach. Repeat doses do not lead to accumulation of the drug.

Distribution.

There is relatively low (15-20%) protein binding of famotidine in the plasma. The plasma half-life after a single oral dose and or multiple repeated doses (for 5 days) was approximately 3 hours.

Biotransformation

Famotidine is metabolised in the liver, with formation of the inactive sulfoxide metabolite.

Elimination

Famotidine is excreted mainly unchanged in the urine (25-60%); a small amount of the drug may be excreted as sulfoxide.

Linearity/non-linearity

Famotidine displays linear kinetics.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose hydrate

Polysorbate 80

Corn Starch

Carnauba wax

Titanium Oxide

Polyethylene glycol 6000

Precipitated calcium carbonate

Microcrystalline cellulose

Talc

Sucrose

Gelatin

Hypromellose 2910

Sodium Lauryl Sulfate

Magnesium Stearate

Sodium Starch Glycolate

Poloxamer 188

hypromellose 2208

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 MONTHS

6.4 Special precautions for storage

Store in a dry place below 30°C.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

The tablets are packed in Al/PVC blisters which are inserted into a carton folder.

6.6 Special precautions for disposal <and other handling>

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

06610/08029/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of latest renewal: Oct 19, 2021

10. DATE OF REVISION OF THE TEXT

July, 2023