PRODUCT MONOGRAPH

ACID CONTROL

Famotidine Tablets USP

10 mg

Histamine H_2-Receptor Antagonist

APOTEX INC.
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Toronto, Ontario
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Famotidine Tablets USP

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of administration	Dosage form / strength	All nonmedicinal ingredients
Oral	Film-coated tablet / 10 mg	Carnauba wax, colloidal silicon dioxide, croscarmellose sodium, ferric oxide red, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

INDICATIONS AND CLINICAL USE

ACID CONTROL (famotidine) is indicated for:

- the treatment of the following conditions where a controlled reduction of gastric secretion is required, such as acid indigestion, heartburn, sour or upset stomach;
- prevention of acid indigestion, heartburn, sour or upset stomach when associated with the consumption of food and/or beverage including nocturnal symptoms associated with the evening meal and expected to cause sleep disturbance.

CONTRAINDICATIONS

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.

Cross sensitivity in this class of compounds has been observed. Therefore, ACID CONTROL should not be administered to patients with a history of hypersensitivity to other H_2-receptor antagonists.

WARNINGS AND PRECAUTIONS

General

In clinical trials, patients with other underlying acid gastrointestinal diseases (e.g. duodenal ulcer, gastric ulcer) did not experience complications; in general, they did not exhibit a clinically significant deterioration in their condition. However, if patients have difficulty or pain on swallowing, severe vomiting, melaena (black stools) choking or chest pain, or if abdominal

discomfort persists, patients should consult a physician to determine the underlying cause. Symptomatic response to therapy with ACID CONTROL (famotidine) does not preclude the presence of gastric malignancy.

Patients with severe coexisting illness should consult a physician before commencing therapy with ACID CONTROL.

Patients consuming nonsteroidal anti-inflammatory drugs may have dyspepsia as a side effect of these medicines and should consult a physician or a pharmacist before taking ACID CONTROL.

Patients over 40 who are experiencing heartburn for the first time, and patients who have noticed unintentional weight loss should consult a physician before using the product.

Therapy should not exceed two weeks of continuous treatment without medical consultation.

Gastrointestinal

Patients with a previous history of ulcer disease complications, those who are experiencing unintended weight loss in association with dyspeptic symptoms, and those who are middle-aged or older with new or recently changed dyspeptic symptoms should consult a physician before commencing therapy with ACID CONTROL.

Renal

Patients with severe kidney disease should consult a physician before commencing therapy with ACID CONTROL. A dosage adjustment may be necessary in patients with moderate or severe renal impairment (creatinine clearance less than 60 mL/min/1.48m^2).

Since CNS adverse effects have been reported in patients with moderate and severe renal insufficiency, longer intervals between doses or lower doses may need to be used in patients with moderate (creatinine clearance 30 to 50 mL/min) or severe (creatinine clearance <30 mL/min) renal insufficiency to adjust for the longer elimination half-life of famotidine (see DOSAGE AND ADMINISTRATION, Dosage Adjustment for Patients with Moderate or Severe Renal Insufficiency)

Special Populations

Pregnant Women: Reproductive studies have been performed in rats and rabbits at oral doses of up to 2000 and 500 mg/kg/day, respectively (approximately 2500 and 625 times the maximum recommended prescription human dose [80 mg], respectively), and have revealed no evidence of impaired fertility or harm to the fetus due to famotidine. There are, however, no adequate or well-controlled studies in pregnant women.

Since the safe use of famotidine in pregnant women has not been established, pregnant women should not use ACID CONTROL unless directed otherwise by a physician.

Nursing Women: Famotidine is detectable in human milk. Nursing mothers should either stop this drug or should stop nursing.

Pediatrics (< 12 years of age): Safety and effectiveness in children have not been established. ACID CONTROL should not be administered to children under 12 years of age.

Geriatrics: No dosage adjustment is required based on age (see ACTION AND CLINICAL PHARMACOLOGY, Pharmacokinetics).

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Famotidine has been demonstrated to be generally well tolerated. Adverse reactions reported in > 1% of patients were headache and dizziness. These occurred with comparable frequency in patients treated with placebo.

Clinical Trial Adverse Drug Reactions

Adverse Drug Reactions were evaluated in 28 clinical trials with more than 13, 000 patients. See Table in Post-Market Adverse Reactions that correlates adverse drug reactions seen post-market by frequency found in clinical trials.

Abnormal Hematologic and Clinical Chemistry Findings

Laboratory parameters may be affected during treatment with famotidine, but the changes are usually not considered serious. Among the laboratory changes that were reported during clinical trials were increases in AST, ALT, and WBC count, and decreases in hemoglobin and hematocrit. These changes were rarely of clinical significance.

No famotidine-treated patients/subjects had to be discontinued from therapy because of laboratory adverse experiences.

Post-Market Adverse Drug Reactions

During marketed use of prescription doses, which are higher than those recommended for non-prescription use, the following adverse reactions have been reported; urticaria, liver enzymes abnormalities, cholestatic jaundice, asthenia, fatigue, somnolence, abdominal discomfort and pain, abdominal pain upper, diarrhoea, dry mouth, nausea, vomiting, pruritus, rash, hypersensitivity, malaise, anaphylaxis, angioedema. Toxic epidermal necrolysis has been reported very rarely with H_2-receptor antagonists.

The following adverse reactions have been reported; however, a causal relationship to therapy with famotidine has not been established: agitation, confusion, hallucinations, grand mal seizures, rare cases of impotence, thrombocytopenia, pancytopenia, leukopenia and agranulocytosis.

Gynecomastia has been reported rarely. In most cases that were followed up, it was reversible after discontinuing treatment.

Post-Market Data

Adverse drug reactions (ADRs) identified during Post-marketing experience with famotidine are

included in Table 1 below. The frequencies are provided according to the following convention based on spontaneous reporting rates:

Very common ≥1/10
Common ≥1/100 and <1/10
Rare ≥1/10,000 and < 1/1,000
Very rare <1/10,000
Not known (cannot be estimated from the available data)

Table 1: Adverse Drug Reactions Identified during Post-Marketing Experience with Famotidine for OTC use by Frequency Category Estimated from Clinical Trials

SOC	Frequency Category	
Adverse Event Preferred Term	Clinical Trials	Spontaneous Reporting Rates
Nervous System Disorders		
Dizziness	Uncommon*	Very rare
Asthenia, Fatigue	Uncommon*	Very rare
Somnolence	Rare	Very rare
Gastrointestinal Disorders		
Abdominal discomfort and pain	Uncommon*	Very rare
Abdominal pain upper	Not known	Very rare
Diarrhea	Uncommon*	Very rare
Dry mouth	Rare*	Very rare
Nausea	Uncommon*	Very rare
Vomiting	Uncommon*	Very rare
Skin and Subcutaneous Tissue Disorders		
Pruritus	Rare *	Very rare
Rash	Uncommon*	Very rare
Urticaria	Not known	Very rare
Immune System Disorders		
Hypersensitivity	Not known	Very rare
Anaphylactic reactions	Not known	Very rare
Angioedema	Not known	Very rare
General Disorders and Administrative Site Conditions		
Malaise	Not known	Very rare
*not significantly greater than Placebo ($p<0.05$)		

In the above table, ADRs in the first frequency category column are presented based on incidence in adequately designed clinical trials or epidemiology studies, if available, or when incidence is unavailable, frequency category is listed as 'Not known'. In the second frequency category column the same ADRs are presented frequency categories estimated from spontaneous reporting rates where the numerator represents total number reported Company Adverse Events under given Preferred Terms or medical concept and denominator represents exposure data calculated from sales data.

DRUG INTERACTIONS

Overview

Studies with famotidine in man, in animal models, and *in vitro* have shown no significant interference with the disposition of compounds metabolized by the hepatic microsomal enzymes,

e.g., cytochrome P450 system. Compounds tested in man have included warfarin, theophylline, phenytoin, diazepam, aminopyrine and antipyrine. Indocyanine green as an index of hepatic blood flow and/or hepatic drug extraction has been tested and no significant effects have been found.

Concomitant use of aluminum hydroxide/magnesium hydroxide at commonly used doses, does not influence the pharmacodynamics or bioavailability of famotidine. Famotidine does not affect gastric alcohol dehydrogenase and, consequently, blood ethanol levels.

Patients should consult a physician before using this product together with any of the following drugs:

Itraconazole
Concomitant use of famotidine with the antifungal agent itraconazole results in significantly reduced peak and trough plasma concentrations of itraconazole, which may result in reduced antifungal efficacy.

Calcium carbonate
The hypophosphatemic effect of calcium carbonate is attenuated with concomitant use of H2-antagonists in patients undergoing chronic hemodialysis.

Drug-Food Interactions
Not known.

Drug-Herb Interactions
Not known

Drug-Laboratory Interactions
Not known

Drug-Lifestyle Interactions
Not known

DOSAGE AND ADMINISTRATION

Dosing Considerations
Antacids may be given concomitantly if needed. It is not appropriate to use this product and other H2 Receptor Antagonists concomitantly.

Recommended Dose and Dosage Adjustment
Adults and children 12 years of age or older:

For symptom relief: one tablet (10 mg), as required.

For prevention of acid-related symptoms associated with the consumption of food and/or beverage: one tablet (10 mg) 10 to 15 minutes before eating food or drinking beverages that cause

heartburn.

Tablet to be swallowed whole with a glass of water. Repeat if symptoms return, up to a maximum of 2 tablets (20 mg in total) in a 24-hour period.

Therapy should not exceed two weeks of continuous treatment without medical consultation.

Dosage Adjustment for Patients with Moderate or Severe Renal Insufficiency
Patients with severe kidney disease should consult a physician before commencing therapy with ACID CONTROL. A dosage adjustment may be necessary in patients with moderate or severe renal impairment (creatinine clearance less than 60 mL/min/1.48m^2). In patients with moderate (creatinine clearance 30 to 50 mL/min), the elimination half-life of famotidine is increased. For patients with severe renal insufficiency, it may exceed 20 hours, reaching approximately 24 hours in anuric patients. Since CNS adverse reactions have been reported in patients with moderate and severe renal insufficiency, to avoid excess accumulation of the drug in patients with moderate or severe renal insufficiency, the dose of famotidine may be reduced to half the dose or the dosing interval may be prolonged to 36 to 48 hours as indicated by the patient's clinical response.

OVERDOSAGE

There is no experience to date with deliberate overdosage. Doses of up to 800 mg/day have been employed in patients with pathological hypersecretory conditions with no serious adverse effects. In the event of overdosage, treatment should be symptomatic and supportive. Unabsorbed material should be removed from the gastrointestinal tract, the patient should be monitored, and supportive therapy should be employed.

The oral LD_{50} of famotidine in male and female rats and mice was >5000 mg/kg.

For management of a suspected drug overdose, contact your regional Poison Control Centre immediately.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action
Famotidine is a competitive inhibitor of histamine H_2-receptors. The primary clinically important pharmacologic activity of famotidine is inhibition of gastric juice secretion. Famotidine reduces the acid and pepsin content, as well as the volume, of basal, nocturnal, and stimulated gastric secretion.

Pharmacodynamics
In both normal volunteers and hypersecretors, famotidine inhibited basal nocturnal and daytime gastric secretion, as well as secretion stimulated by a variety of stimuli, such as pentagastrin and food.

After oral administration, a dose-response relationship was clearly demonstrated from 0.5 and 10 mg famotidine in terms of raising gastric pH between and after meals. Famotidine doses of 2.5 to 10 mg were demonstrated to produce a statistically significant effect on gastric pH as compared to placebo. The onset of effect for the 5 and 10 mg doses was seen at approximately 1.5 hours postdose while that of the 2.5 mg dose was not seen until 2.5 hours postdose. The maximum effect, as measured by peak mean pH value, occurred at 3.5 hours. Famotidine was well-tolerated at these dose levels. Pharmacodynamic data from nighttime studies show that the activity of the 10 mg dose continues for up to 12 hours postdose.

Fasting and postprandial serum gastrin levels may be slightly elevated during periods of drug antisecretory effect, and with chronic therapy an increase in gastric bacterial flora may occur. Gastric emptying and exocrine pancreatic function are not affected by famotidine.

Other Effects
Systemic pharmacologic effects of famotidine involving the CNS, cardiovascular, respiratory or endocrine systems have not been found to date. Serum prolactin levels do not rise after intravenous bolus doses of 20 mg of famotidine and no antiandrogenic effects have been detected.

Pharmacokinetics

Famotidine is incompletely absorbed. The bioavailability of oral doses is 40 to 45%. Famotidine undergoes minimal first-pass metabolism. After oral doses, peak plasma levels occur in 1 to 3 hours. C_{max} values of 41 ng/mL and 40 ng/mL for the 10 mg film-coated tablets and the 10 mg chewable tablets, respectively, were found in one bioequivalence study. For additional information, see **Comparative Bioavailability Studies** below.

Absorption: The absorption of famotidine was studied in two animal species. Absorption was 28% in the rat and 43% in the dog.

Distribution: The distribution of famotidine was studied in two animal species. The plasma half-life in dogs was 2.5 hours, which was unchanged after repeated doses, indicating no tendency for the drug to accumulate. In rats, the highest levels of radioactivity after an oral dose of famotidine were found in the gastrointestinal tract, kidneys, liver, submandibular glands, arteries, epiphyseal membrane, fascia, and uvea. The distribution pattern was not affected on repeated dosing. Famotidine did not effectively cross the blood-brain or placental barrier of rats. It was present in rat milk.

Metabolism: The only metabolite of famotidine in rat and dog urine was the sulfoxide derivative, which was present in minor amounts.

Excretion: Urinary and fecal excretion of radioactivity in rats accounted for 28% and 70%, respectively, of an oral dose, compared to 83% and 17% respectively, of an intravenous dose. About 2.4% of the dose in rats was excreted in the bile. Dogs excreted 45% of an oral dose in the urine, compared to 100% of an intravenous dose.

Effects on Liver Microsomal Drug-Metabolizing Enzymes
Famotidine did not affect pentobarbital or hexobarbital sleeping times and it did not affect ascorbic acid excretion, suggesting that famotidine does not induce drug-metabolizing enzymes. Famotidine caused none of the changes induced by cimetidine on the pharmacokinetics of diazepam, warfarin, and propranolol. Famotidine produced only minimal suppression of aminopyrine and diazepam N-demethylase activity *in vitro*, and showed little affinity for testosterone hydroxylases of mouse *liver in vitro*.

Gastrointestinal Effects other than Antisecretory
Famotidine prevented gastric erosions induced in rats by cold restraint, water immersion, pyloric ligation, or drugs such as acetylsalicylic acid, histamine or prednisolone; also duodenal ulcers caused by cysteamine and mepirizole. It also significantly accelerated the healing of the gastric lesions induced by acetic acid and the duodenal ulcers produced by mepirizole.
The antiulcer effect of famotidine plus magnesium and aluminum hydroxides was greater than the sum of the effects of these drugs used separately.

Famotidine inhibited the gastric lesions and hemorrhage resulting from blood removal and histamine injection in anesthetized rats.

In normal rats, famotidine had no effect on the concentration of gastric mucosal histamine, but it did reduce the levels of cAMP, particularly in response to histamine stimulation.

In anaesthetized cats, famotidine had no effect on the intragastric electropotential when tested at intragastric doses more than ten-fold greater than those required to block gastric secretion maximally.

Cardiorenal Effects
The cardiorenal effects of famotidine were studied in dogs and rats. Ten mg/kg of famotidine administered orally were without effect on the blood pressure of spontaneously hypertensive rats. In anaesthetized dogs, intravenous administration of 1.0 and 4.0 mg/kg of famotidine was without effect on cardiovascular parameters relating to the autonomic nervous system, blood pressure, heart rate, or respiratory function. In conscious dogs, an oral dose of 10 mg/kg was without diuretic effect.

Central Nervous System Effects
The effects of famotidine on the central nervous system were studied in squirrel monkeys, mice, and cats. In monkeys famotidine had a bidirectional effect on lever pressing (avoidance response) causing an increase at the low dose (1.0 mg/kg p.o.) and a small decrease at 9 mg/kg. In mice following intraperitoneal administration of 6 to 150 mg/kg no overt behavioral signs or symptoms of central nervous system activity were observed. In mice famotidine was not active as an antagonist of the CNS actions of TRH, neurotensin, substance P, or amphetamine. Famotidine was free of major or minor tranquilizing, anticonvulsant, anticholinergic, ganglionic blocking, or dopaminergic activity. In cats, famotidine did not affect the EEG or arousal response but did prolong the duration of hippocampal after-discharge. Only 4% of the plasma concentration of the drug was detected in the cerebrospinal fluid.

STORAGE AND STABILITY

Store at room temperature (15°C to 30°C). Protect from light and moisture.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each film-coated tablet for oral administration contains 10 mg of famotidine and the following non-medicinal ingredients: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, ferric oxide red, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

ACID CONTROL 10 mg: pink, square, biconvex, film-coated tablets engraved ‘10’ on one side and plain on the other side. Available in unit dose packages of 2, 6, 12 and 30tablets.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

I. DRUG SUBSTANCE

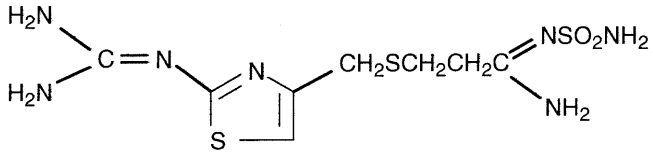
Proper name: famotidine

Chemical name: N'-(aminosulfonyl)-3-[[[2-[(diaminomethylene)amino]- 4-thiazolyl]methyl]thio] Propanimidamide.

Molecular formula: $C_8H_{15}N_7O_2S_3$

Molecular weight: 337.44 g/mol

Structural formula:



Description: Famotidine is a white to pale yellow crystalline compound that is freely soluble in glacial acetic acid, slightly soluble in methanol, very slightly soluble in water and practically insoluble in ethanol.

DETAILED PHARMACOLOGY

ANIMAL PHARMACOLOGY

Famotidine inhibits gastric secretion evoked by histamine and other secretagogues. In dogs, the ED_{50} was 0.03 mg/kg after oral or intravenous administration of famotidine. An oral dose of 2.1 mg/kg in dogs inhibited gastric secretion for at least 24 hours. An oral dose of 3 mg/kg one hour prior to feeding inhibited the acid response in dogs during a 4-hour post feeding period by an average of 96%.

Mechanism of Action

Famotidine is a specific, competitive, H_2-receptor antagonist. There was no effect *in vitro* on responses mediated by H_1-histamine, beta$_1$-adrenergic, or cholinergic receptors. Famotidine was inactive in radioligand binding to dopaminergic, neuroleptic, serotonergic, adrenergic, cholinergic, and purinergic sites. Famotidine was also inactive in an androgen receptor assay.

The interaction between famotidine and H_2-receptors is tissue-dependent. In guinea pig lungs and rabbit gastric glands the effects of famotidine were surmountable and readily reversible on washout, indicating classic competitive inhibition at the H_2-receptor sites. However, in guinea pig atria, famotidine acted as a non-competitive H_2 antagonist, and recovery after washout of famotidine was retarded.

TOXICOLOGY

Acute Toxicity

Species	Sex	Route	LD_{50} (mg/kg)
Mouse	M	P.O.*	4,684
	F	P.O.*	3,233
Mouse	M	I.V. (4%)	254
	F	I.V. (4%)	358
Rat	M	P.O.*	4,907
	F	P.O.*	4,049
Rat	M	I.P.	987
	F	I.P.	814

*In solution (acidic, 50˚C to 55˚C deionized water).

Subacute and Chronic Toxicity

Famotidine is well tolerated by both rats and dogs at doses of 2 g/kg twice a day orally in subacute studies and at doses up to 1000 or 2000 mg/kg/day for one year in these species. Eosinophilic

cytoplasmic granularity of gastric chief cells was seen at a higher incidence in rats given 200 mg/kg/day or more of the compound compared to controls. This is considered as a secondary effect due to the exaggerated pharmacologic activity of the compound and at these extremely high dosage levels and is considered of no toxicologic significance. In a 106-week study in rats designed to study the carcinogenic potential of the compound, this gastric change did not progress to hyperplasia or neoplasia. Similarly, mice (given the compound for 92 weeks) showed no evidence of a neoplastic potential. Based on the results from studies performed using pharmacologically-related compounds, this change was fully reversible.

Intravenous administration of famotidine was well tolerated by rats for 13 weeks at dosage levels of up to 20 mg/kg/day and by dogs, except for occasional emesis, at dosage levels of up to 10 mg/kg/day for 5 to 26 weeks.

Reproduction Studies
In studies with rats given oral doses of up to 2000 mg/kg/day or intravenous doses of up to 200 mg/kg/day (approximately 2500 and 250 times the maximum recommended prescription human dose, respectively), fertility and reproductive performance were not affected.
Famotidine given orally to pregnant rats up to 2000 mg/kg/day or intravenously at dosage levels up to 200 mg/kg/day, from Days 7 to 17 of pregnancy did not reveal any evidence of embryolethality or teratogenicity.
Oral administration of famotidine to pregnant rabbits from Days 6 to 18 of pregnancy at dosage levels up to 500 mg/kg/day revealed no evidence of embryolethality or teratogenicity.

Mutagenicity
Famotidine was tested in a reverse-mutation test (Ames test) using *Salmonella typhimurium* and *Escherichia coli* with and without metabolic activation. No mutagenic potential was seen. These same studies were performed with famotidine/sodium, nitrite reaction mixture and C-nitroso derivatives of famotidine and they were also negative. Famotidine and C-nitroso derivatives of famotidine were tested in the rec-assay using *Bacillus subtilis* H17 and M45 and the tests were negative for DNA-damaging capacity of the compounds. In *in vivo* studies in mice, a micronucleus test and a chromosomal aberration test, no evidence of a mutagenic effect was seen.

Carcinogenicity
A 92-week oral carcinogenicity study was conducted in mice at doses of 20, 200 and 2000 mg/kg/day. No evidence of a carcinogenic potential was seen. A 106-week oral carcinogenicity study in rats given doses of 20, 200 and 2000 mg/kg/day did not reveal any carcinogenic potential for famotidine.

Special Studies
The effects of famotidine on the thyroid of rats were evaluated after five weeks of oral administration at doses up to 2000 mg/kg/day. No evidence of treatment-related alterations of serum thyroid hormone levels, thyroid weight or the microscopic appearance were seen after administration of famotidine.

In immunogenicity studies, no effect on the production of IgE antibodies was seen in the sera of mice which were injected, once intraperitoneally, with famotidine alone (up to 2 mg/8 mL/kg) or

coupled with either mouse serum albumin or ovalbumin. The sera were used to measure passive cutaneous anaphylaxis in rats which were then challenged with solutions of antigens similar to those antigens used for the initial dose in mice. Similarly, no evidence of an anaphylactic reaction was seen in guinea pigs challenged intravenously with famotidine after initiating doses (three times, subcutaneously, at six-day intervals) of up to 10 mg/mL.

REFERENCES

1. Hayakawa A, Che K, Miyoshi A, Harasawa S, Miwa T, Makabatake T. Properties of famotidine in relation to safety. Ital J Gastroenterol 1984; 16: 174 - 176.

2. McCallum RW, Kuljian B, Chremos AN, Tupy-Visich MA, Huber PB. Prolonged gastric antisecretory effect of a novel H_2-receptor inhibitor, MK-208. Gastroenterology (in Soc. Proc.) 1983; 84: 1245.

3. Barzaghi N, Gratti G, Crema F, Perucca E. Impaired bioavailability of famotidine given concurrently with a potent antacid. J Clin Pharmacol 1989; 29: 670 - 72.

4. Echizen H, Ishizaki T. Clinical pharmacokinetics of famotidine. Clin Pharmacokin 1991; 21: 178 - 94.

5. Lin JH, Chremos AN, Kanovsky SM, Schwartz S, Yeh KC, Kahn J. Effects of antacids and food on absorption of famotidine. Br J Clin Pharmacol 1987; 24: 551 - 53.

6. Product Monograph, PEPCID AC® (famotidine tablets) Film Coated Tablets 10 mg, McNeil Consumer Healthcare, Division of Johnson & Johnson Inc., Date of Revision: May 24, 2019; Control Number: 225990.

PART III: CONSUMER INFORMATION

ACID CONTROL
Famotidine Tablets USP

This leaflet is part III of a three-part "Product Monograph" published when ACID CONTROL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ACID CONTROL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
ACID CONTROL provides fast effective relief from heartburn, acid indigestion and upset or sour stomach due to excess stomach acid. In addition, when taken 10 to 15 minutes before a meal, ACID CONTROL can actually prevent heartburn before it starts.

Day or night, ACID CONTROL relieves and prevents these symptoms brought on by consuming food and/or beverage. One tablet, taken before your evening meal can prevent night-time heartburn symptoms so you can sleep through the night.

What it does:
Unlike antacids which neutralize existing stomach acid, but allow stomach acid to continue to be produced, ACID CONTROL reduces the production of excess stomach acid which can lead to heartburn and upset stomach. This enables ACID CONTROL to provide long lasting acid control, day or night.

When it should not be used:
- If you are allergic to Famotidine or any nonmedicinal ingredients (see complete list) in this product;
- If you have had an allergic reaction to another product that contains an acid reducer (e.g. ranitidine);
- With another acid reducer.

What the medicinal ingredient is:
Each film-coated tablet of ACID CONTROL contains 10 mg of famotidine.

What the important nonmedicinal ingredients are:
Film-coated tablets contain the following non-medicinal ingredients: carnauba wax, colloidal silicon dioxide, croscarmellose sodium, ferric oxide red, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

What dosage forms it comes in:
ACID CONTROL is available as a film-coated tablet to ease swallowing.

WARNINGS AND PRECAUTIONS

This medicine may not be suitable for some people.

BEFORE you use ACID CONTROL talk to your doctor or pharmacist if:
- You are pregnant or breast-feeding;
- You have difficulty or pain on swallowing, severe vomiting, black stools, choking, or persistent stomach pains/ discomfort;
- You have kidney disease, as you may need a dose adjustment;
- You have any other severe illnesses;
- You are over 40 years of age and you are experiencing new or recently changed symptoms of acid indigestion or heartburn;
- You are taking any prescription or over-the-counter medications such as nonsteroidal anti-inflammatory drugs [NSAIDs] (because NSAIDs may be causing your symptoms);
- You have a previous history of ulcer disease complications;
- You are experiencing unintended weight loss in association with your symptoms of acid indigestion or heartburn.
- You have heartburn with light headedness, sweating and dizziness;
- You have chest or shoulder pain with shortness of breath, sweating, pain spreading to arms or neck, or light headedness.

HEARTBURN WARNINGS
Heartburn and acid indigestion are common; however heartburn can be a sign of a more serious medical condition, which requires medical intervention. **Stop use of this product and any other nonprescription products you are taking for heartburn and see your doctor or pharmacist if**:
- you have had heartburn for over 3 months and haven't seen a doctor about it
- your heartburn continues, worsens or returns after using heartburn medication every day for 14 days.
- you often need to use heartburn medication for 14 consecutive days (for example every 6 weeks or more frequently).
- your heartburn continues after using this or any other nonprescription heartburn product.

INTERACTIONS WITH THIS MEDICATION

Before taking ACID CONTROL talk to your doctor or pharmacist if:

- You are using Itraconazole (for fungal infections).
- You are using calcium carbonate

PROPER USE OF THIS MEDICATION

Usual dose:
Adults and children 12 years of age or older: For relief of symptoms, swallow one (1) tablet with full glass of water. For prevention of acid-related symptoms brought on by consuming food and/or beverage swallow one (1) tablet with full glass of water 10 to 15 minutes before eating. If symptoms return, you may take another tablet. Do not take more than two tablets during a 24-hour period. If symptoms get worse or persist for more than two consecutive weeks, or if new symptoms develop, stop use and consult your physician.

WHAT ELSE CAN BE DONE TO AVOID SYMPTOMS

- Do not lie down soon after eating.
- If you are overweight, lose weight.
- If you smoke, stop or cut down.
- Avoid foods known to cause symptoms, and avoid or limit foods such as caffeine, chocolate, fatty foods, spicy foods and alcohol.
- Do not eat just before bedtime.
- Raise the head of your bed.
- Wear loose fitting clothing around your stomach.

Overdose:

If you think you have taken too much ACID CONTROL, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

ACID CONTROL is generally well tolerated.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptoms / effects		Talk with your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Very	Dizziness and	√		
Rare	sleepiness			
Very Rare	Stomach pain, diarrhea, dry mouth, nausea, and vomiting		√	
Very Rare	Allergic reactions such as rash, hives, swelling, itching and difficulty to breath		√	

This is not a complete list of side effects. If you have any unexpected effects after taking ACID CONTROL contact your doctor or pharmacist.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

- Store these tablets at room temperature (15°C to 30°C) and protect from light and moisture.
- It is advisable to keep blisters in carton until all tablets are used.
- Keep this and all medicines out of the reach and sight of children.

MORE INFORMATION

If you want more information about ACID CONTROL:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (https://health-products.canada.ca/dpd-bdpp/index-eng.jsp); Find the Consumer Information on the manufacturer's website http://www.apotex.ca/products, or by calling 1-800-667-4708.

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