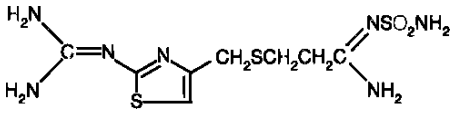
MERCK & CO., INC.
West Point, PA 19486, USA XXXXXXX

PEPCID®
(FAMOTIDINE) TABLETS
PEPCID®
(FAMOTIDINE) FOR ORAL SUSPENSION
PEPCID RPD™
(FAMOTIDINE) ORALLY DISINTEGRATING TABLETS

DESCRIPTION

The active ingredient in PEPCID* (Famotidine) is a histamine H_2-receptor antagonist. Famotidine is *N′*-(aminosulfonyl)-3-[[[2-[(diaminomethylene)amino]-4-thiazolyl]methyl]thio]propanimidamide. The empirical formula of famotidine is $C_8H_{15}N_7O_2S_3$ and its molecular weight is 337.43. Its structural formula is:



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.

Each tablet for oral administration contains either 20 mg or 40 mg of famotidine and the following inactive ingredients: hydroxypropyl cellulose, hydroxypropyl methylcellulose, iron oxides, magnesium stearate, microcrystalline cellulose, corn starch, talc, and titanium dioxide.

Each PEPCID RPD Orally Disintegrating Tablet for oral administration contains either 20 mg or 40 mg of famotidine and the following inactive ingredients: aspartame, mint flavor, gelatin, mannitol, red ferric oxide, and xanthan gum.

Each 5 mL of the oral suspension when prepared as directed contains 40 mg of famotidine and the following inactive ingredients: citric acid, flavors, microcrystalline cellulose and carboxymethylcellulose sodium, sucrose and xanthan gum. Added as preservatives are sodium benzoate 0.1%, sodium methylparaben 0.1%, and sodium propylparaben 0.02%.

CLINICAL PHARMACOLOGY

GI Effects

PEPCID is a competitive inhibitor of histamine H_2-receptors. The primary clinically important pharmacologic activity of PEPCID is inhibition of gastric secretion. Both the acid concentration and volume of gastric secretion are suppressed by PEPCID, while changes in pepsin secretion are proportional to volume output.

In normal volunteers and hypersecretors, PEPCID inhibited basal and nocturnal gastric secretion, as well as secretion stimulated by food and pentagastrin. After oral administration, the onset of the antisecretory effect occurred within one hour; the maximum effect was dose-dependent, occurring within one to three hours. Duration of inhibition of secretion by doses of 20 and 40 mg was 10 to 12 hours.

Single evening oral doses of 20 and 40 mg inhibited basal and nocturnal acid secretion in all subjects; mean nocturnal gastric acid secretion was inhibited by 86% and 94%, respectively, for a period of at least 10 hours. The same doses given in the morning suppressed food-stimulated acid secretion in all subjects. The mean suppression was 76% and 84%, respectively, 3 to 5 hours after administration, and 25% and 30%, respectively, 8 to 10 hours after administration. In some subjects who received the 20 mg dose, however, the antisecretory effect was dissipated within 6-8 hours. There was no cumulative effect

*Registered trademark of MERCK & CO., Inc.

with repeated doses. The nocturnal intragastric pH was raised by evening doses of 20 and 40 mg of PEPCID to mean values of 5.0 and 6.4, respectively. When PEPCID was given after breakfast, the basal daytime interdigestive pH at 3 and 8 hours after 20 or 40 mg of PEPCID was raised to about 5.

PEPCID had little or no effect on fasting or postprandial serum gastrin levels. Gastric emptying and exocrine pancreatic function were not affected by PEPCID.

Other Effects

Systemic effects of PEPCID in the CNS, cardiovascular, respiratory or endocrine systems were not noted in clinical pharmacology studies. Also, no antiandrogenic effects were noted. (See ADVERSE REACTIONS.) Serum hormone levels, including prolactin, cortisol, thyroxine (T_4), and testosterone, were not altered after treatment with PEPCID.

Pharmacokinetics

PEPCID is incompletely absorbed. The bioavailability of oral doses is 40-45%. PEPCID Tablets, PEPCID for Oral Suspension and PEPCID RPD Orally Disintegrating Tablets are bioequivalent. Bioavailability may be slightly increased by food, or slightly decreased by antacids; however, these effects are of no clinical consequence. PEPCID undergoes minimal first-pass metabolism. After oral doses, peak plasma levels occur at 1-3 hours. Plasma levels after multiple doses are similar to those after single doses. Fifteen to 20% of PEPCID in plasma is protein bound. PEPCID has an elimination half-life of 2.5-3.5 hours. PEPCID is eliminated by renal (65-70%) and metabolic (30-35%) routes. Renal clearance is 250-450 mL/min, indicating some tubular excretion. Twenty-five to 30% of an oral dose and 65-70% of an intravenous dose are recovered in the urine as unchanged compound. The only metabolite identified in man is the S-oxide.

There is a close relationship between creatinine clearance values and the elimination half-life of PEPCID. In patients with severe renal insufficiency, i.e., creatinine clearance less than 10 mL/min, the elimination half-life of PEPCID may exceed 20 hours and adjustment of dose or dosing intervals may be necessary (see PRECAUTIONS, DOSAGE AND ADMINISTRATION).

In elderly patients, there are no clinically significant age-related changes in the pharmacokinetics of PEPCID.

Clinical Studies

Duodenal Ulcer

In a U.S. multicenter, double-blind study in outpatients with endoscopically confirmed duodenal ulcer, orally administered PEPCID was compared to placebo. As shown in Table 1, 70% of patients treated with PEPCID 40 mg h.s. were healed by week 4.

Table 1
Outpatients with Endoscopically
Confirmed Healed Duodenal Ulcers

	PEPCID 40 mg h.s. (N = 89)	PEPCID 20 mg b.i.d. (N = 84)	Placebo h.s. (N = 97)
Week 2	**32%	**38%	17%
Week 4	**70%	**67%	31%

** Statistically significantly different than placebo ($p<0.001$)

Patients not healed by week 4 were continued in the study. By week 8, 83% of patients treated with PEPCID had healed versus 45% of patients treated with placebo. The incidence of ulcer healing with PEPCID was significantly higher than with placebo at each time point based on proportion of endoscopically confirmed healed ulcers.

In this study, time to relief of daytime and nocturnal pain was significantly shorter for patients receiving PEPCID than for patients receiving placebo; patients receiving PEPCID also took less antacid than the patients receiving placebo.

Long-Term Maintenance

Treatment of Duodenal Ulcers

PEPCID, 20 mg p.o. h.s. was compared to placebo h.s. as maintenance therapy in two double-blind, multicenter studies of patients with endoscopically confirmed healed duodenal ulcers. In the U.S. study

the observed ulcer incidence within 12 months in patients treated with placebo was 2.4 times greater than in the patients treated with PEPCID. The 89 patients treated with PEPCID had a cumulative observed ulcer incidence of 23.4% compared to an observed ulcer incidence of 56.6% in the 89 patients receiving placebo ($p<0.01$). These results were confirmed in an international study where the cumulative observed ulcer incidence within 12 months in the 307 patients treated with PEPCID was 35.7%, compared to an incidence of 75.5% in the 325 patients treated with placebo ($p<0.01$).

Gastric Ulcer

In both a U.S. and an international multicenter, double-blind study in patients with endoscopically confirmed active benign gastric ulcer, orally administered PEPCID, 40 mg h.s., was compared to placebo h.s. Antacids were permitted during the studies, but consumption was not significantly different between the PEPCID and placebo groups. As shown in Table 2, the incidence of ulcer healing (dropouts counted as unhealed) with PEPCID was statistically significantly better than placebo at weeks 6 and 8 in the U.S. study, and at weeks 4, 6 and 8 in the international study, based on the number of ulcers that healed, confirmed by endoscopy.

Table 2
Patients with Endoscopically
Confirmed Healed Gastric Ulcers

	U.S. Study		International Study	
	PEPCID 40 mg h.s. (N = 74)	Placebo h.s. (N = 75)	PEPCID 40 mg h.s. (N = 149)	Placebo h.s. (N = 145)
Week 4	45%	39%	†47%	31%
Week 6	†66%	44%	†65%	46%
Week 8	***78%	64%	†80%	54%

***,† Statistically significantly better than placebo ($p\leq0.05$, $p\leq0.01$ respectively)

Time to complete relief of daytime and nighttime pain was statistically significantly shorter for patients receiving PEPCID than for patients receiving placebo; however, in neither study was there a statistically significant difference in the proportion of patients whose pain was relieved by the end of the study (week 8).

Gastroesophageal Reflux Disease (GERD)

Orally administered PEPCID was compared to placebo in a U.S. study that enrolled patients with symptoms of GERD and without endoscopic evidence of erosion or ulceration of the esophagus. PEPCID 20 mg b.i.d. was statistically significantly superior to 40 mg h.s. and to placebo in providing a successful symptomatic outcome, defined as moderate or excellent improvement of symptoms (Table 3).

Table 3
% Successful Symptomatic Outcome

	PEPCID 20 mg b.i.d. (N = 154)	PEPCID 40 mg h.s. (N = 149)	Placebo (N = 73)
Week 6	82††	69	62

†† $p\leq0.01$ vs Placebo

By two weeks of treatment symptomatic success was observed in a greater percentage of patients taking PEPCID 20 mg b.i.d. compared to placebo ($p\leq0.01$).

Symptomatic improvement and healing of endoscopically verified erosion and ulceration were studied in two additional trials. Healing was defined as complete resolution of all erosions or ulcerations visible with endoscopy. The U.S. study comparing PEPCID 40 mg p.o. b.i.d. to placebo and PEPCID 20 mg p.o.

b.i.d. showed a significantly greater percentage of healing for PEPCID 40 mg b.i.d. at weeks 6 and 12 (Table 4).

Table 4
% Endoscopic Healing - U.S. Study

	PEPCID 40 mg b.i.d. (N = 127)	PEPCID 20 mg b.i.d. (N = 125)	Placebo (N = 66)
Week 6	48†††,‡‡	32	18
Week 12	69†††,‡	54†††	29

†††p≤0.01 vs Placebo
‡p≤0.05 vs PEPCID 20 mg b.i.d.
‡‡p≤0.01 vs PEPCID 20 mg b.i.d.

As compared to placebo, patients who received PEPCID had faster relief of daytime and nighttime heartburn and a greater percentage of patients experienced complete relief of nighttime heartburn. These differences were statistically significant.

In the international study, when PEPCID 40 mg p.o. b.i.d., was compared to ranitidine 150 mg p.o. b.i.d., a statistically significantly greater percentage of healing was observed with PEPCID 40 mg b.i.d. at week 12 (Table 5). There was, however, no significant difference among treatments in symptom relief.

Table 5
% Endoscopic Healing - International Study

	PEPCID 40 mg b.i.d. (N = 175)	PEPCID 20 mg b.i.d. (N = 93)	Ranitidine 150 mg b.i.d. (N = 172)
Week 6	48	52	42
Week 12	71‡‡‡	68	60

‡‡‡p≤0.05 vs Ranitidine 150 mg b.i.d.

Pathological Hypersecretory Conditions (e.g., Zollinger-Ellison Syndrome, Multiple Endocrine Adenomas)

In studies of patients with pathological hypersecretory conditions such as Zollinger-Ellison Syndrome with or without multiple endocrine adenomas, PEPCID significantly inhibited gastric acid secretion and controlled associated symptoms. Orally administered doses from 20 to 160 mg q 6 h maintained basal acid secretion below 10 mEq/hr; initial doses were titrated to the individual patient need and subsequent adjustments were necessary with time in some patients. PEPCID was well tolerated at these high dose levels for prolonged periods (greater than 12 months) in eight patients, and there were no cases reported of gynecomastia, increased prolactin levels, or impotence which were considered to be due to the drug.

INDICATIONS AND USAGE

PEPCID is indicated in:

1. *Short term treatment of active duodenal ulcer.* Most patients heal within 4 weeks; there is rarely reason to use PEPCID at full dosage for longer than 6 to 8 weeks. Studies have not assessed the safety of famotidine in uncomplicated active duodenal ulcer for periods of more than eight weeks.

2. *Maintenance therapy for duodenal ulcer patients at reduced dosage after healing of an active ulcer.* Controlled studies have not extended beyond one year.

3. *Short term treatment of active benign gastric ulcer.* Most patients heal within 6 weeks. Studies have not assessed the safety or efficacy of famotidine in uncomplicated active benign gastric ulcer for periods of more than 8 weeks.

4. *Short term treatment of gastroesophageal reflux disease (GERD).* PEPCID is indicated for short term treatment of patients with symptoms of GERD (see CLINICAL PHARMACOLOGY, *Clinical Studies*).

PEPCID is also indicated for the short term treatment of esophagitis due to GERD including erosive or ulcerative disease diagnosed by endoscopy (see CLINICAL PHARMACOLOGY, *Clinical Studies*).

5. *Treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison Syndrome, multiple endocrine adenomas).*

CONTRAINDICATIONS

Hypersensitivity to any component of these products.

PRECAUTIONS

General

Symptomatic response to therapy with PEPCID 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. (See CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION.) However, currently, no drug-related toxicity has been found with high plasma concentrations of famotidine.

Information for Patients

The patient should be instructed to shake the oral suspension vigorously for 5-10 seconds prior to each use. Unused constituted oral suspension should be discarded after 30 days.

Patients should be instructed to leave the PEPCID RPD Orally Disintegrating Tablet in the unopened package until the time of use. Patients should then open the tablet blister pack with dry hands, place the tablet on the tongue to dissolve and be swallowed with saliva. No water is needed for taking the tablet.

Phenylketonurics: Phenylketonuric patients should be informed that PEPCID RPD contains phenylalanine 1.05 mg per 20 mg orally disintegrating tablet and 2.10 mg per 40 mg orally disintegrating tablet.

Drug Interactions

No drug interactions have been identified. 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 include warfarin, theophylline, phenytoin, diazepam, aminopyrine and antipyrine. Indocyanine green as an index of hepatic drug extraction has been tested and no significant effects have been found.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 106 week study in rats and a 92 week study in mice given oral doses of up to 2000 mg/kg/day (approximately 2500 times the recommended human dose for active duodenal ulcer), there was no evidence of carcinogenic potential for PEPCID.

Famotidine was negative in the microbial mutagen test (Ames test) using *Salmonella typhimurium* and *Escherichia coli* with or without rat liver enzyme activation at concentrations up to 10,000 mcg/plate. In *in vivo* studies in mice, with a micronucleus test and a chromosomal aberration test, no evidence of a mutagenic effect was observed.

In studies with rats given oral doses of up to 2000 mg/kg/day or intravenous doses of up to 200 mg/kg/day, fertility and reproductive performance were not affected.

Pregnancy

Pregnancy Category B

Reproductive studies have been performed in rats and rabbits at oral doses of up to 2000 and 500 mg/kg/day, respectively, and in both species at I.V. doses of up to 200 mg/kg/day, and have revealed no significant evidence of impaired fertility or harm to the fetus due to PEPCID. While no direct fetotoxic effects have been observed, sporadic abortions occurring only in mothers displaying marked decreased food intake were seen in some rabbits at oral doses of 200 mg/kg/day (250 times the usual human dose) or higher. There are, however, no adequate or well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, 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 PEPCID, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in children have not been established.

Use in Elderly Patients

No dosage adjustment is required based on age (see CLINICAL PHARMACOLOGY, *Pharmacokinetics*). Dosage adjustment in the case of severe renal impairment may be necessary.

ADVERSE REACTIONS

The adverse reactions listed below have been reported during domestic and international clinical trials in approximately 2500 patients. In those controlled clinical trials in which PEPCID Tablets were compared to placebo, the incidence of adverse experiences in the group which received PEPCID Tablets, 40 mg at bedtime, was similar to that in the placebo group.

The following adverse reactions have been reported to occur in more than 1% of patients on therapy with PEPCID in controlled clinical trials, and may be causally related to the drug: headache (4.7%), dizziness (1.3%), constipation (1.2%) and diarrhea (1.7%).

The following other adverse reactions have been reported infrequently in clinical trials or since the drug was marketed. The relationship to therapy with PEPCID has been unclear in many cases. Within each category the adverse reactions are listed in order of decreasing severity:

Body as a Whole: fever, asthenia, fatigue

Cardiovascular: arrhythmia, AV block, palpitation

Gastrointestinal: cholestatic jaundice, liver enzyme abnormalities, vomiting, nausea, abdominal discomfort, anorexia, dry mouth

Hematologic: rare cases of agranulocytosis, pancytopenia, leukopenia, thrombocytopenia

Hypersensitivity: anaphylaxis, angioedema, orbital or facial edema, urticaria, rash, conjunctival injection

Musculoskeletal: musculoskeletal pain including muscle cramps, arthralgia

Nervous System/Psychiatric: grand mal seizure; psychic disturbances, which were reversible in cases for which follow-up was obtained, including hallucinations, confusion, agitation, depression, anxiety, decreased libido; paresthesia; insomnia; somnolence

Respiratory: bronchospasm

Skin: toxic epidermal necrolysis (very rare), alopecia, acne, pruritus, dry skin, flushing

Special Senses: tinnitus, taste disorder

Other: rare cases of impotence and rare cases of gynecomastia have been reported; however, in controlled clinical trials, the incidences were not greater than those seen with placebo.

The adverse reactions reported for PEPCID Tablets may also occur with PEPCID for Oral Suspension and PEPCID RPD Orally Disintegrating Tablets.

OVERDOSAGE

There is no experience to date with deliberate overdosage. Oral doses of up to 640 mg/day have been given to 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 greater than 3000 mg/kg and the minimum lethal acute oral dose in dogs exceeded 2000 mg/kg. Famotidine did not produce overt effects at high oral doses in mice, rats, cats and dogs, but induced significant anorexia and growth depression in rabbits starting with 200 mg/kg/day orally. The intravenous LD_{50} of famotidine for mice and rats ranged from 254-563 mg/kg and the minimum lethal single I.V. dose in dogs was approximately 300 mg/kg. Signs of acute intoxication in I.V. treated dogs were emesis, restlessness, pallor of mucous membranes or redness of mouth and ears, hypotension, tachycardia and collapse.

PEPCID® (Famotidine) Tablets XXXXXXX
PEPCID® (Famotidine) for Oral Suspension
PEPCID RPD™ (Famotidine) Orally Disintegrating Tablets

DOSAGE AND ADMINISTRATION

Duodenal Ulcer

Acute Therapy: The recommended adult oral dosage for active duodenal ulcer is 40 mg once a day at bedtime. Most patients heal within 4 weeks; there is rarely reason to use PEPCID at full dosage for longer than 6 to 8 weeks. A regimen of 20 mg b.i.d. is also effective.

Maintenance Therapy: The recommended oral dose is 20 mg once a day at bedtime.

Benign Gastric Ulcer

Acute Therapy: The recommended adult oral dosage for active benign gastric ulcer is 40 mg once a day at bedtime.

Gastroesophageal Reflux Disease (GERD)

The recommended oral dosage for treatment of patients with symptoms of GERD is 20 mg b.i.d. for up to 6 weeks. The recommended oral dosage for the treatment of patients with esophagitis including erosions and ulcerations and accompanying symptoms due to GERD is 20 or 40 mg b.i.d. for up to 12 weeks (see CLINICAL PHARMACOLOGY, *Clinical Studies*).

Pathological Hypersecretory Conditions (e.g., Zollinger-Ellison Syndrome, Multiple Endocrine Adenomas)

The dosage of PEPCID in patients with pathological hypersecretory conditions varies with the individual patient. The recommended adult oral starting dose for pathological hypersecretory conditions is 20 mg q 6 h. In some patients, a higher starting dose may be required. Doses should be adjusted to individual patient needs and should continue as long as clinically indicated. Doses up to 160 mg q 6 h have been administered to some patients with severe Zollinger-Ellison Syndrome.

Oral Suspension

PEPCID for Oral Suspension may be substituted for PEPCID Tablets in any of the above indications. Each five mL contains 40 mg of famotidine after constitution of the powder with 46 mL of Purified Water as directed.

Directions for Preparing PEPCID for Oral Suspension

Prepare suspension at time of dispensing. Slowly add 46 mL of Purified Water. Shake vigorously for 5-10 seconds immediately after adding the water and immediately before use.

Stability of PEPCID for Oral Suspension

Unused constituted oral suspension should be discarded after 30 days.

Orally Disintegrating Tablets

PEPCID RPD–Orally Disintegrating Tablets may be substituted for PEPCID Tablets in any of the above indications at the same recommended dosages.

PEPCID RPD Orally Disintegrating Tablets rapidly disintegrate on the tongue. No water is needed for taking the tablet. Patients should be instructed to open the tablet blister pack with dry hands, place the tablet on the tongue to disintegrate and be swallowed with saliva.

Concomitant Use of Antacids

Antacids may be given concomitantly if needed.

Dosage Adjustment for Patients with Severe Renal Insufficiency

In patients with severe renal insufficiency, i.e., with a creatinine clearance less than 10 mL/min, the elimination half-life of PEPCID may exceed 20 hours, reaching approximately 24 hours in anuric patients. Although no relationship of adverse effects to high plasma levels has been established, to avoid excess accumulation of the drug, the dose of PEPCID may be reduced to 20 mg h.s. or the dosing interval may be prolonged to 36-48 hours as indicated by the patient's clinical response.

HOW SUPPLIED

No. 3535 — PEPCID Tablets, 20 mg, are beige colored, U-shaped, film-coated tablets coded MSD 963 on one side and PEPCID on the other. They are supplied as follows:

NDC 0006-0963-31 unit of use bottles of 30
(6505-01-260-0902, 20 mg 30's)
NDC 0006-0963-94 unit of use bottles of 90
NDC 0006-0963-58 unit of use bottles of 100
NDC 0006-0963-28 unit dose package of 100
(6505-01-310-4178, 20 mg individually sealed 100's)
NDC 0006-0963-82 bottles of 1,000
NDC 0006-0963-87 bottles of 10,000

PEPCID® (Famotidine) Tablets XXXXXXX
PEPCID® (Famotidine) for Oral Suspension
PEPCID RPD™ (Famotidine) Orally Disintegrating Tablets

(6505-01-379-7902, 20 mg 10,000's)
NDC 0006-0963-72 carton of 25 UNIBLISTER™ cards of 31 tablets each.

No. 3536 — PEPCID Tablets, 40 mg, are light brownish-orange, U-shaped, film-coated tablets coded MSD 964 on one side and PEPCID on the other. They are supplied as follows:
NDC 0006-0964-31 unit of use bottles of 30
(6505-01-257-3164, 40 mg 30's)
NDC 0006-0964-94 unit of use bottles of 90
NDC 0006-0964-58 unit of use bottles of 100
NDC 0006-0964-28 unit dose package of 100
(6505-01-318-0464, 40 mg individually sealed 100's)
NDC 0006-0964-82 bottles of 1,000
NDC 0006-0964-87 bottles of 10,000
(6505-01-379-7900, 40 mg 10,000's)
NDC 0006-0964-72 carton of 25 UNIBLISTER™ cards of 31 tablets each.

No.3553 — PEPCID RPD Orally Disintegrating Tablets, 20 mg, are pale rose colored, hexagonal-shaped, lyophilized tablets measuring 13.1 mm (side to side) and 15.2 mm (point to point), with a mint flavor. They are supplied as follows:
NDC 0006-3553-31 unit dose package of 30
NDC 0006-3553-48 unit dose package of 100
NDC 0006-3553-28 unit dose package of 100.

No.3554 — PEPCID RPD Orally Disintegrating Tablets, 40 mg, are pale rose colored, hexagonal-shaped, lyophilized tablets measuring 15.9 mm (side to side) and 18.4 mm (point to point), with a mint flavor. They are supplied as follows:
NDC 0006-3554-31 unit dose package of 30
NDC 0006-3554-48 unit dose package of 100.

No. 3538 — PEPCID for Oral Suspension is a white to off-white powder containing 400 mg of famotidine for constitution. When constituted as directed, PEPCID for Oral Suspension is a smooth, mobile, off-white, homogeneous suspension with a cherry-banana-mint flavor, containing 40 mg of famotidine per 5 mL.
NDC 0006-3538-92, bottles containing 400 mg famotidine.

Storage

Avoid storage of PEPCID Tablets at temperatures above 40°C (104°F).
Store PEPCID RPD Orally Disintegrating Tablets below 30°C (86°F).
Avoid storage of the powder for oral suspension at temperatures above 40°C (104°F). After constitution store the suspension below 30°C (86°F). Do not freeze. Discard unused suspension after 30 days.

PEPCID (famotidine) Tablets and PEPCID (famotidine) for Oral Suspension are manufactured by:
MERCK & CO., INC., West Point, PA 19486, USA

PEPCID RPD (famotidine) Orally Disintegrating Tablets are manufactured for:
MERCK & CO., INC., West Point, PA 19486, USA
By:
Scherer DDS, Swindon, England and are
Made in England

Issued
Printed in USA