FAMOTIDINE- famotidine tablet, film coated Valu Merchandisers Company

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Famotidine USP, 10 mg

Famotidine USP, 20 mg

PURPOSE

Acid reducer

USES

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

WARNINGS

Allergy alert: Do not use if you are allergic to famotidine or other acid reducers

Do not use

Famotidine USP, 10 mg

- with other acid reducers
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Famotidine USP, 20 mg

- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor.
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness**, **sweating**, or **dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

DIRECTIONS

Famotidine USP, 10 mg

- adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
 - to prevent symptoms, swallow 1 tablet with a glass of water 60 minutes before eating food or drinking beverages that cause heartburn
 - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

Famotidine USP, 20 mg

- adults and children 12 years and over:
 - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
 - to prevent symptoms, swallow 1 tablet with a glass of water at any time from 10 to 60 minutes before eating food or drinking beverages that cause heartburn
 - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

OTHER INFORMATION

- store at 20° to 25°C (68° to 77°F)
- protect from moisture
- read the directions and warnings before use
- keep the carton. It contains important information.
- TAMPER EVIDENT: DO NOT USE IF THE CARTON OR INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.
- TAMPER EVIDENT: DO NOT USE IF THE CARTON OR PRINTED FOIL UNDER CAP IS OPEN OR TORN.

INACTIVE INGREDIENTS

Colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron oxide red (only for Famotidine USP, 10 mg), magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, titanium dioxide

QUESTIONS?

Call **1-800-406-7984**

PATIENT INFORMATION

- **1 tablet** relieves heartburn due to acid indigestion
- Famotidine prevents heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

Tips for Managing Heartburn

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol, and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

PRINCIPAL DISPLAY PANEL

COMPARE TO THE ACTIVE INGREDIENT OF ORIGINAL STRENGTH PEPCID_®AC[†] Best Choice[®] Brand ORIGINAL STRENGTH ACID CONTROLLER FAMOTIDINE TABLETS USP, 10 mg ACID REDUCER Just One Tablet Prevents & Relieves Heartburn Due to Acid Indigestion 30 TABLETS DISTRIBUTED BY: VALU MERCHANDISERS, CO.

5085657/R0411



10 mg, 30's

COMPARE TO THE ACTIVE INGREDIENT OF ORIGINAL STRENGTH PEPCID®AC[†] Best Choice®Brand MAXIMUM STRENGTH ACID CONTROLLER FAMOTIDINE TABLETS USP, 20 mg ACID REDUCER Just One Tablet Prevents & Relieves Heartburn Due to Acid Indigestion 25 TABLETS DISTRIBUTED BY: VALU MERCHANDISERS, CO. 5078117/0310



20 mg, 25's

FAMOTIDINE									
famotidine tablet, film	coated								
Product Informatio	n								
		HUMAN OTC DRUG Item Code (Source) NE				NDC (C20	41.025		
Product Type			ne m	Item Code (Source) NDO			DC:63941-035		
Route of Administration	on	ORAL							
Active Ingredient/A	Active Ingredient/Active Moiety								
Ingredient Name				Basis of S			Strength		
FAMOTIDINE (UNII: 5Q2	2O15J2Z8) (FA	MOTIDINE - UNII:5QZ	O15J2Z8)		FAMOTIDIN	Е	10 mg		
11									
Inactive Ingredient	ts								
		Ingredient Na	me				Strength		
COLLOIDAL SILICON									
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)									
HYPROMELLOSES (UNII: 3NXW29V3WO)									
FERRIC OXIDE RED (UNII: 1K09F3G675)									
MAGNESIUM STEARATE (UNII: 70097M6I30)									
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)									
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)									
STARCH, PREGELATINIZED CORN (UNII: 08232NY3SJ)									
TALC (UNII: 7SEV7J4R1U) TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)									
THANION DIOXIDE (01	NII. IJFIAJ V 2J	r)							
Product Character	istics								
Color					no score				
Shape	ROUN				8mm				
Flavor	KO ON.	OUND Size Imprint Code			035				
Contains						035			
Contains									
Packaging									
	De al	Package Description Marketing Start Date				Marketing End Date			
# Item Code1 NDC:63941-035-31		kage DescriptionMarketing StLISTER PACK			Marketing End Date				
I INDC:03941-035-31	30 111 1 11	ISTER PACK							
Marketing Info	rmation								
Marketing Category	Applicatio	tion Number or Monograph Citation Marketing Start Date Marke				ing End Date			
ANDA	ANDA09028	3		06/25/20	10				

Product Information	1							
Product Type		HUMAN OTC DRU	JG	Item Code (Source) NDC			DC:63941-036	
Route of Administration	1	ORAL						
Active Ingredient/Active Ingre	ctive Moi	ety						
	Ing	redient Name			Basis of S	Strength	Strength	
FAMO TIDINE (UNII: 5QZC)15J2Z8) (FA	MOTIDINE - UNII:5	QZO15J2Z8)	FAMOTIDINE		20 mg	
Inactive Ingredients								
		Ingredient	Name				Strength	
COLLOIDAL SILICON D								
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)								
MAGNESIUM STEARATE (UNII: 70097M6I30)								
HYDROXYPROPYL CELI								
STARCH, PREGELATINIZ								
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)								
TALC (UNII: 7SEV7J4R1U)		D \						
TITANIUM DIO XIDE (UNI HYPROMELLOSES (UNII:								
Product Characteris	tics							
	stics white		Score			no score		
Color		D	Score Size			no score 8mm		
Color Shape	white			de				
Color Shape Flavor	white		Size	de		8 m m		
Color Shape Flavor Contains	white		Size	de		8 m m		
Color Shape Flavor Contains Packaging	white ROUNI		Size Imprint Co	de Aarketing Start D	Date	8 m m	End Date	
Color Shape Flavor Contains Packaging # Item Code	white ROUNI	kage Description	Size Imprint Co		Date	8mm 036	End Date	
Color Shape Flavor Contains Packaging I Item Code 1 NDC:63941-036-25	white ROUNI 25 in 1 BC	kage Description	Size Imprint Co		Date	8mm 036	End Date	
Product Characteris Color Shape Flavor Contains Packaging # Item Code 1 NDC:63941-036-25 Marketing Infori Marketing Category	white ROUNI 25 in 1 BO	kage Description	Size Imprint Co 1 N	Aarketing Start D	Date ing Start Dat	8mm 036 Marketing	End Date	

Labeler - Valu Merchandisers Company (868703513)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment						
Name	Address	ID/FEI	Business Operations			
Ohm Laboratories Inc.		184769029	manufacture(63941-035, 63941-036)			

Revised: 2/2013

Valu Merchandisers Company