FAMOTIDINE- famotidine tablet
Wockhardt USA LLC.

Famotidine Tablets USP, 20 mg

OTC - ACTIVE INGREDIENT SECTION

Famotidine USP 20 mg

OTC - PURPOSE SECTION

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

● 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.

● if you have kidney disease, except under the advice and supervision of a doctor

● with other acid reducers

ASK A DOCTOR BEFORE USE IF YOU HAVE

● 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

● frequent **chest pain**

● frequent wheezing, particularly with heartburn

● unexplained weight loss

● nausea or vomiting

● stomach pain

Stop use and ask a doctor if

● your heartburn continues or worsens

● you need to take this product for more than 14 days

PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding, ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS

- 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

- read the directions and warnings before use
- store at 20°-25°C (68°-77°F)
- keep the carton. It contains important information.
- protect from moisture

INACTIVE INGREDIENT

Hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, magnesium stearate, polyethylene glycol, pregelatinized starch, talc and titanium dioxide.

QUESTIONS OR COMMENTS

Call **1-800-346-6854**

Manufactured by:

Wockhardt Limited,

Mumbai, India.

Distributed by:

Wockhardt USA LLC.

20 Waterview Blvd.

Parsippany, NJ 07054

USA.

Iss.130810

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Famotidine Tablets USP, 20 mg (OTC)

20 mg – Acid reducer

64679-374-05

FAMOTIDINE

famotidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64679-374
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (white)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	W374
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64679-374-01	1 in 1 CARTON	08/06/2010	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:64679-374-08	1 in 1 CARTON	08/06/2010	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:64679-374-05	1 in 1 CARTON	08/06/2010	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:64679-374-07	10 in 1 CARTON	08/06/2010	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:64679-374-00	38000 in 1 DRUM; Type 0: Not a Combination Product	08/06/2010	
6	NDC:64679-374-09	6500 in 1 DRUM; Type 0: Not a Combination Product	08/06/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090837	08/06/2010	

Labeler - Wockhardt USA LLC. (170508365)

Registrant - Wockhardt Limited (650069115)

Establishment

Name	Address	ID/FEI	Business Operations
Wockhardt Limited		916489953	ANALYSIS(64679-374) , LABEL(64679-374) , MANUFACTURE(64679-374) , PACK(64679-374)

Revised: 11/2019 Wockhardt USA LLC.