FAMOTIDINE- famotidine tablet
Wockhardt USA LLC.

Famotidine Tablets USP, 10 mg

OTC - ACTIVE INGREDIENT SECTION

Famotidine USP 10 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.
- 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 **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 25°-30°C (77°-86°F)
- protect from moisture
- keep the carton and package insert. They contain important information.

INACTIVE INGREDIENT

hydroxypropyl cellulose, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, 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.

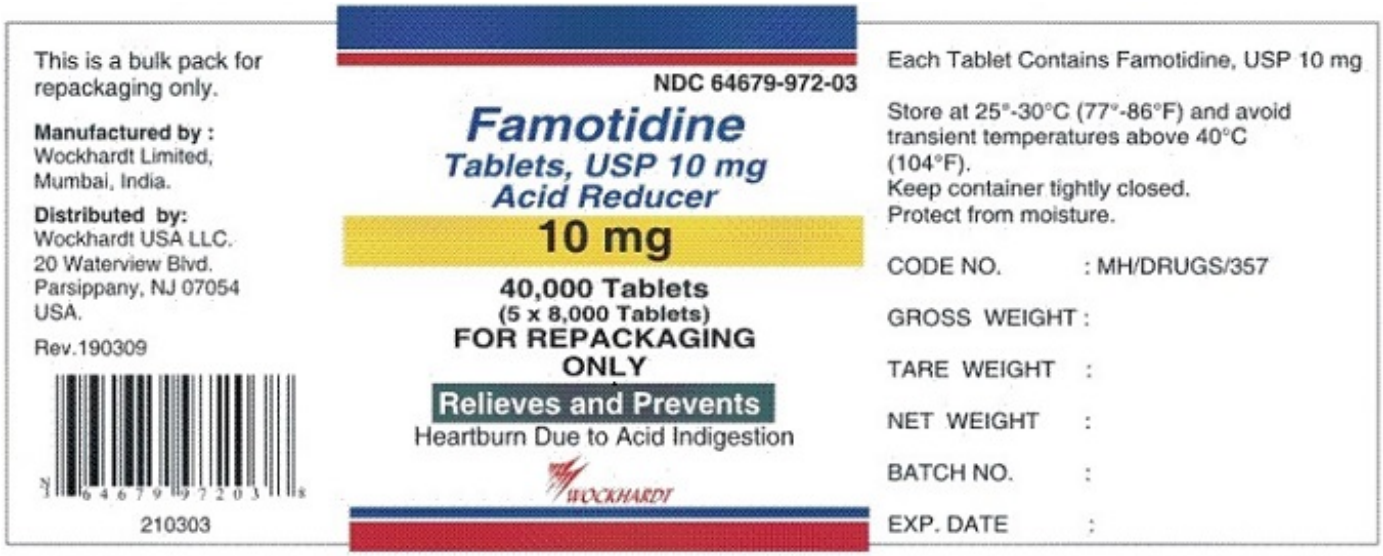
Iss.100510

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Famotidine Tablets USP, 10 mg (OTC)

10 mg – Acid reducer

64679-972-03



FAMOTIDINE

famotidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64679-972
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
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)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	PINK (pink)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	W;972
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64679-972-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2005	
2	NDC:64679-972-02	10 in 1 CARTON	03/07/2005	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:64679-972-00	50000 in 1 DRUM; Type 0: Not a Combination Product	03/07/2005	
4	NDC:64679-972-03	40000 in 1 DRUM; Type 0: Not a Combination Product	03/07/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077146	03/07/2005	

Labeler - Wockhardt USA LLC. (170508365)

Registrant - Wockhardt Limited (650069115)

Establishment

Name	Address	ID/FEI	Business Operations
Wockhardt Limited		916489953	ANALYSIS(64679-972) , LABEL(64679-972) , MANUFACTURE(64679-972) , PACK(64679-972)

Revised: 11/2019 Wockhardt USA LLC.