FAMOTIDINE - ACID CONTROLLER- famotidine tablet, film coated
Ohm Laboratories Inc.

DRUG FACTS

ACTIVE INGREDIENT (IN EACH TABLET)

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

- 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

- 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.** ***(for blister carton)***
- **TAMPER EVIDENT: DO NOT USE IF THE CARTON OR PRINTED FOIL UNDER CAP IS OPEN OR TORN.** ***(for bottle carton/label)***
- **TAMPER EVIDENT: DO NOT USE IF THE PRINTED FOIL UNDER CAP IS OPEN OR TORN.** ***(for SAL/extended label)***

INACTIVE INGREDIENTS

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, titanium dioxide

QUESTIONS?

call **1-800-406-7984**

PATIENT INFORMATION

JUST ONE TABLET prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

See end panel for batch number and expiration date. (for carton only)

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 Maximum Strength Pepcid AC®.

NDC 51660-036-26

ohm®

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: Ohm Laboratories Inc.

5142565/R0517

25's Blister Carton

FAMOTIDINE - ACID CONTROLLER

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51660-036
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	036
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-036-26	25 in 1 BOTTLE; Type 0: Not a Combination Product	05/31/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090283	05/31/2017	

Labeler - Ohm Laboratories Inc. (184769029)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(51660-036)

Revised: 11/2017 Ohm Laboratories Inc.