FAMOTIDINE- famotidine tablet
Ipca Laboratories Limited

Famotidine Tablets USP

Drug Facts:

Active ingredient (in each tablet)

For 10 mg:

Famotidine USP, 10 mg

For 20 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

- ***For 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.
- ***For 20 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.
- if you have kidney disease, except under the advice and supervision of a 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

For 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

For 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 between 20° to 25°C (68° to 77°F)
- protect from moisture
- read the directions and warnings before use

Inactive ingredients

For 10 mg: microcrystalline cellulose, pregelatinized starch, colloidal silicon dioxide, magnesium stearate, hypromellose, hydroxypropyl cellulose, titanium dioxide, polyethylene glycol, talc, ferric iron oxide.

For 20 mg: microcrystalline cellulose, pregelatinized starch, colloidal silicon dioxide, magnesium stearate, hypromellose, hydroxypropyl cellulose, titanium dioxide, polyethylene glycol, talc.

Questions?

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

- **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.

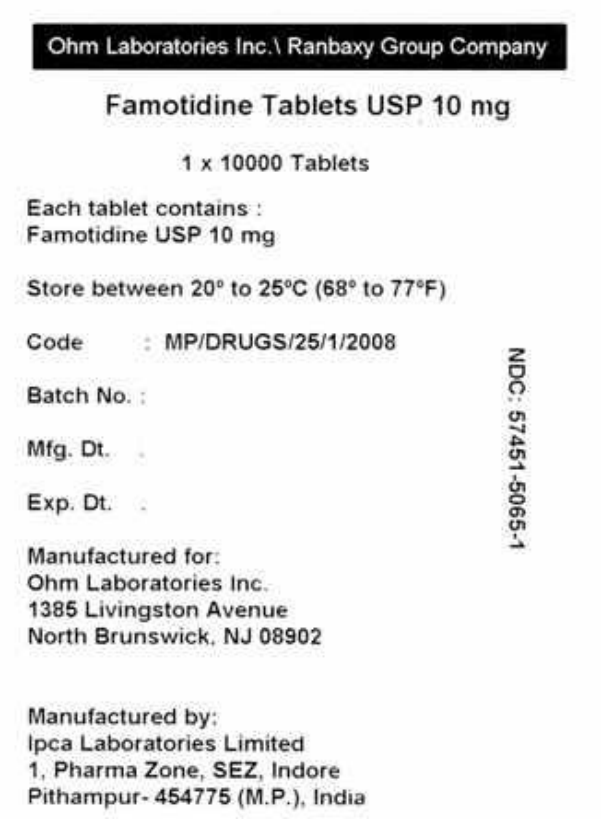
Tips for Managing Heartburn

■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 vegetablets.
■Eat slowly and avoid big meals
■If overweight, lose weight
■Quit smoking

Manufactured for:
Ohm Laboratories Inc.
14 Terminal Road
New Brunswick, NJ 08901
Manufactured by:
Ipca Laboratories Limited
1, Pharma Zone, SEZ Indore,
Pithampur 454775, (M.P.), India

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ohm Laboratories Inc.\Ranbaxy Group Company
NDC: 57451-5065-1
Famotidine Tablets USP 10 mg
1x 10000 Tablets
Each tablet contains:
Famotidine USP 10 mg
Store between 20° to 25°C (68° to 77°F)
Code : MP/DRUGS/25/1/2008
Batch No. :
Mfg. Dt. :
Exp. Dt. :
Manufactured for:
Ohm Laboratories Inc.
14 Terminal Road
New Brunswick, NJ 08901
Manufactured by:
Ipca Laboratories Limited
1, Pharma Zone, SEZ, Indore
Pithampur- 454775 (M.P.), India



Ohm Laboratories Inc.\Ranbaxy Group Company

NDC: 57451-5066-1

Famotidine Tablets USP 20 mg

1x 10000 Tablets

Each tablet contains:

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Code : MP/DRUGS/25/1/2008

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Mfg. Dt. :

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Manufactured for:

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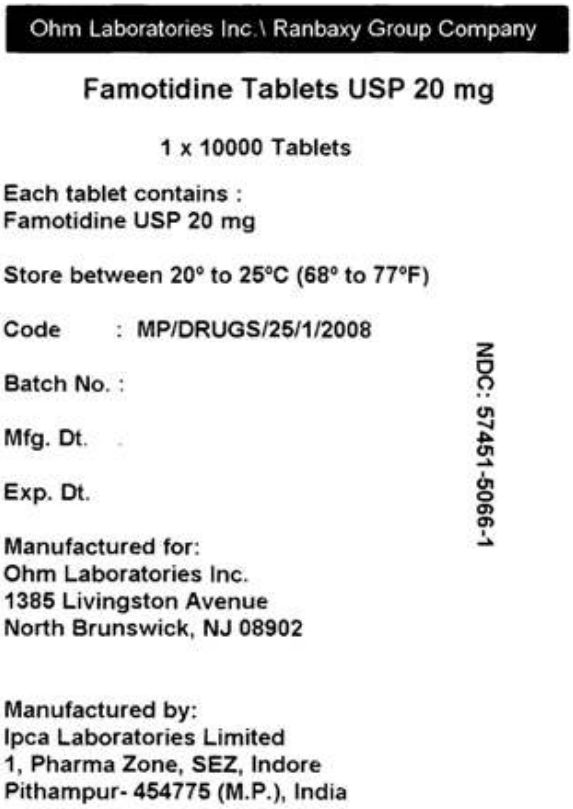

FAMOTIDINE

famotidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57451-5065
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)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	035
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57451-5065-1	10000 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090283	06/25/2010	

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famotidine tablet

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MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	

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:57451-5066-1	10000 in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090283	07/23/2010	

Labeler - Ipca Laboratories Limited (862179827)

Registrant - Ipca Laboratories Limited (650387009)

Establishment

Name	Address	ID/FEI	Business Operations
Ipca Laboratories Limited		677600550	Manufacture

Revised: 3/2011 Ipca Laboratories Limited