

FAMOTIDINE - famotidine tablet
WOCKHARDT LIMITED

Famotidine Tablets, USP
20 mg

Drugs Facts

Active ingredient (in each tablets)
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

- 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

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.

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 ingredients

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

<p>Do not use if printed foil seal under bottle cap is open or torn.</p>	<p>NDC 64679-374-05</p>	<p>MAXIMUM STRENGTH Famotidine Tablets, USP</p>	<p>20 mg</p>	<p>Acid Reducer <i>Just One Tablet</i></p>	<p><i>Prevents & Relieves Heartburn Due to Acid Indigestion</i></p>	<p>500 Tablets</p>	<p>WOCKHARDT</p>	
	<p>Iss.100610</p>	<p>Active ingredient (in each tablet) Famotidine 20 mg.....</p>	<p>Purpose Acid reducer</p>	<p>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</p> <p>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. 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. 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.</p>				
<p>Manufactured by: Wockhardt Limited, Mumbai, India.</p>		<p>Distributed by: Wockhardt USA LLC. 20 Waterview Blvd. Parsippany, NJ 07054 USA.</p>		<p>Lot: _____ Exp.: _____</p>		<p>3 6 4 6 7 9 3 7 4 0 5 4</p>		<p>Non Varnish Area</p>

Do not use if carton is open or printed foil seal under bottle cap is open or torn.

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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



Non Varnish Area

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20 Waterview Blvd.,
Parlisperry, NJ 07054
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NDC 64679-374-05

MAXIMUM STRENGTH
Famotidine
Tablets, USP

20 mg

Acid Reducer

Just One Tablet

*Prevents & Relieves Heartburn
Due to Acid Indigestion*



500 Tablets
(500 Doses)

FAMOTIDINE

famotidine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55648-374
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white (white)	Score	no score
Shape	ROUND (barrel shaped)	Size	9mm
Flavor		Imprint Code	W374
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55648-374-01	1 in 1 CARTON		
1		30 in 1 BOTTLE		
2	NDC:55648-374-08	1 in 1 CARTON		
2		30 in 1 BOTTLE		
3	NDC:55648-374-05	1 in 1 CARTON		
3		500 in 1 BOTTLE		
4	NDC:55648-374-07	10 in 1 CARTON		
4		10 in 1 BLISTER PACK		
5	NDC:55648-374-00	38000 in 1 DRUM		
6	NDC:55648-374-09	6500 in 1 DRUM		

Marketing Information

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

Labeler - WOCKHARDT LIMITED (650069115)

Revised: 8/2012

WOCKHARDT LIMITED