FAMOTIDINE- famotidine tablet, film coated
Praxis, LLC

Famotidine Tablet

20 mg

For Hospital Use Only

Drug Facts

Active ingredient (in each tablet)

Famotidine 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.
- 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
- kidney disease

Ask a doctor or pharmacist before use if you aretaking a prescription drug. Acid reducers may interact with certain prescription drugs.

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

- **Use as directed per healthcare professional.**
- 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)
- protect from moisture

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

Questions or comments?

1-800-397-9228

GLUTEN FREE

How Supplied

NDC 68094-054-65
Unit Dose Packages of 200 Tablets
(20 × 10) per Carton

Packaged by:
Precision Dose, Inc.
South Beloit, IL 61080

For inquiries call Precision Dose, Inc.
at 1-800-397-9228 or email
druginfo@precisiondose.com

LI1465 Rev. 08/23

PRINCIPAL DISPLAY PANEL - 20 mg Tablet Blister Pack Carton Label

Precision Dose™

NDC 68094-054-65
Unit Dose

Famotidine
Tablets 20 mg

200 Tablets
(20 x 10)
(in each tablet)
Famotidine 20 mg
Acid reducer

Directions
To relieve symptoms, swallow 1 tablet
with a glass of water. Do not chew.

GLUTEN FREE

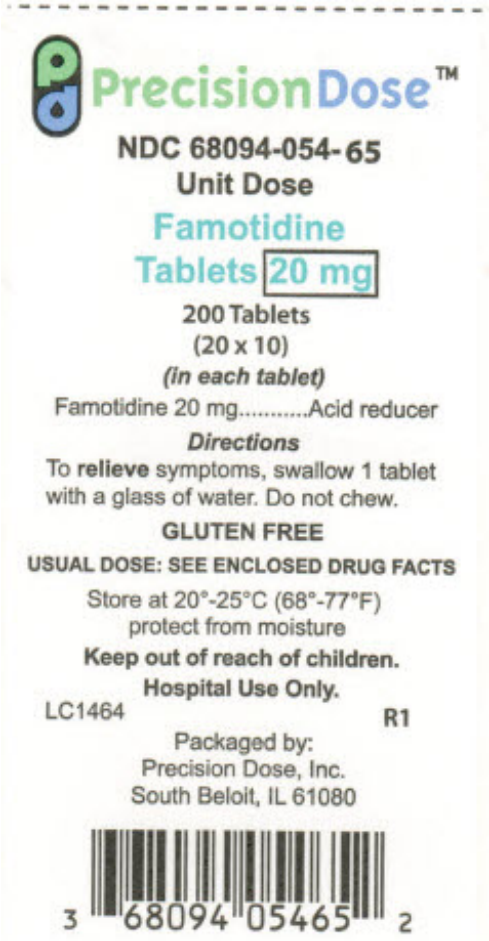
USUAL DOSE: SEE ENCLOSED DRUG FACTS

Store at 20°-25°C (68°-77°F)
protect from moisture

Keep out of reach of children.
Hospital Use Only.

LC1464
R1

Packaged by:
Precision Dose, Inc.
South Beloit, IL 61080



FAMOTIDINE

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59368-280
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	L194
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59368-280-01	1 in 1 CARTON	03/28/2024	
1		200 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077351	03/28/2024	

Labeler - Praxis, LLC (016329513)

Establishment

Name	Address	ID/FEI	Business Operations
Praxis, LLC		016329513	manufacture(59368-280) , label(59368-280) , pack(59368-280)

Revised: 1/2023 Praxis, LLC