

FAMOTIDINE - famotidine tablet, film coated
CVS Pharmacy, Inc.

Drug Facts

Active ingredient (in each tablet)

Famotidine USP 10 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 are

taking 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 (1-800-222-1222) 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 **15 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
- keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)
- protect from moisture

Inactive ingredients

carnauba wax, corn starch, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide, sodium starch glycolate, talc and titanium dioxide.

Questions or comments?

call **1-855-274-4122**

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

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

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

Distributed by:

CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

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CVS.com®

1-800-SHOP CVS

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (30 Tablets Container Label)

**♥CVS
Health®**

NDC 69842-928-84

Original Strength

Acid Reducer

FAMOTIDINE

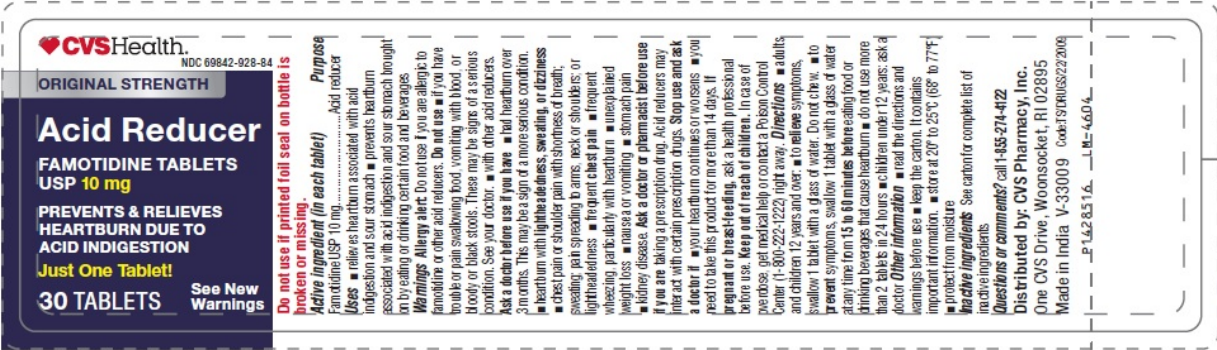
TABLETS USP 10 mg

PREVENTS & RELIEVES HEARTBURN DUE TO ACID INDIGESTION

Just One Tablet!

SEE NEW WARNINGS

30 TABLETS



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL -10 mg (30 Tablets Container Carton Label)



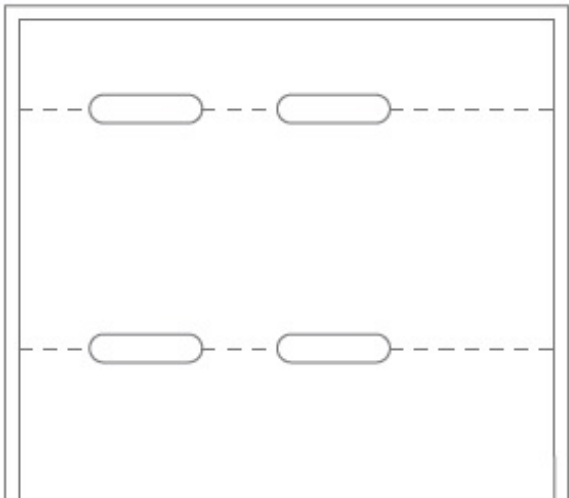
Compare to the active ingredient in
Original Strength Zantac 360[®] TM *
NDC 69842-928-84

ORIGINAL STRENGTH NEW FORMULA
Acid Reducer
FAMOTIDINE TABLETS USP 10 mg
Just One Tablet!
PREVENTS & RELIEVES HEARTBURN
Due to acid indigestion

SEE NEW WARNINGS

Actual Size

30 TABLETS



LEBG927M1

CVSHealth.

ORIGINAL STRENGTH

NEW FORMULA

Acid Reducer

FAMOTIDINE TABLETS USP 10 mg

CVSHealth.

Compare to the active ingredient in,
Original Strength Zantac 360™

NDC 60842-028-841

ORIGINAL STRENGTH

NEW FORMULA

Acid Reducer

FAMOTIDINE TABLETS USP 10 mg

Just One Tablet!

PREVENTS
& RELIEVES
HEARTBURN
Due to acid indigestion

Actual Size

30 TABLETS

See New Warnings

Package Contains
One Bottle

Actual Size

- Tip: To relieve heartburn
- Drink 8 ounces or more of water
 - Do not eat or drink within 1 hour of bedtime
 - Do not eat or drink within 1 hour of bedtime
 - Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, alcohol, and carbonated drinks
 - Eat slowly and avoid large meals
 - Lose weight, if overweight
 - Quit smoking

The patient is advised to read the accompanying patient information leaflet (PIL) for important information.

DO NOT USE IF CAPTION IS OPEN OR IF PRINTED PILL SEAL UNDER BOTTLE CAP IS BROKEN OR TORN.

Drug Facts (continued)

Other information:

Keep out of reach of children. Use only as directed. Do not use if the seal is broken or the cap is open.

Warnings:

Do not use if you are allergic to famotidine or any of the ingredients. Do not use if you are pregnant or breastfeeding. Do not use if you are taking other medications that may interact with famotidine.

Directions:

Take one tablet twice a day, before and after meals. Do not take more than one tablet at a time.

Other information:

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CVS Quality

Code 13100222000

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-928
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND (biconvex)	Size	5mm
Flavor		Imprint Code	CC;58
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-928-84	1 in 1 CARTON	06/28/2021	
1		30 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	ANDA206531	06/28/2021	

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(69842-928) , MANUFACTURE(69842-928)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(69842-928) , MANUFACTURE(69842-928)

Revised: 12/2021

CVS Pharmacy, Inc.