# FAMOTIDINE - ACID CONTROLLER- famotidine tablet, film coated WinCo Foods, LLC

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Famotidine - Acid Controller

Drug Facts

## Active ingredient (in each tablet)

Famotidine, USP 10 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

Famotidine USP, 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.

## Famotidine USP, 20 mg

- 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**

Famotidine USP, 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

#### Famotidine USP, 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 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.

## **Inactive ingredients**

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, iron oxide red (only for Famotidine USP, 10 mg), magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, pregelatinized starch, talc, titanium dioxide

## Questions?

or to report an adverse event call **800-824-1706** Monday - Friday 9am - 4pm MST

**DISTRIBUTED BY:** WINCO FOODS, LLC, BOISE, ID 83704

## PRINCIPAL DISPLAY PANEL - 10 mg Blister Pack Carton

\*Compare to the active ingredient in PEPCID AC® Original Strength

WinCo™ FOODS ORIGINAL STRENGTH Acid Controller

FAMOTIDINE TABLETS,

USP 10 mg/ ACID REDUCER JUST ONE TABLET Prevents & Relieves Heartburn Due to Acid Indigestion

30

Tablets



- nausea or vomiting a unexplained weight loss heartburn
- frequent wheezing, particularly with
  - trequent chest pain

#### Ask a doctor before use if you have

serious condition. See your doctor. black stools. These may be signs of a food, vomiting with blood, or bloody or

- If you have trouble or pain swallowing
  - with other acid reducers Do not use

to famotidine or other acid reducers Allergy alert: Do not use if you are allergic Warnings

#### peverages

by eating or drinking certain food and indigestion and sour stomach brought on brevents heartburn associated with acid

- indigestion and sour stomach relieves heartburn associated with acid

Active ingredient

Purpose

■ had heartburn over 3 months. This may be Drug Facts (continued)

■ heartburn with lightheadedness,

a sign of a more serious condition.

cyildren under 12 years: ask a doctor

■ do not use more than 2 tablets in

beverages that cause heartburn

with a glass of water 60 minutes

■ to prevent symptoms, swallow 1 tablet

with a glass of water. Do not chew,

■ to relieve symptoms, swallow 1 tablet

before eating food or drinking

■ adults and children 12 years and over:

Control Center right away (1-800-222-1222).

Keep out of reach of children. In case of

you need to take this product for more

ueck or shoulders; or lightheadedness

of breath; sweating; pain spreading to arms, cuest bsin or shoulder pain with shortness

your neartburn continues or worsens

Stop use and ask a doctor if

sweating, or dizziness

overdose, get medical help or contact a Poison

If pregnant or breast-feeding, ask a health

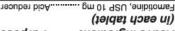
24 hours

Directions

brofessional before use.

than 14 days





Drug Facts

# **ORIGINAL STRENGTH Acid Controller**

WinCo FOODS

30 TABLETS

\*Compare to the active ingredient in PEPCID AC® Original Strength

WinCo

ORIGINAL STRENGTH Acid Controller

**FAMOTIDINE TABLETS,** USP 10 mg/ ACID REDUCER

JUST ONE TABLET Prevents & Relieves Heartburn Due to Acid Indigestion



Batch No.

Varnish Free

■ Do not lie flat or bend over after eating ■ Do not wear tight-fitting clothing around the stomach ■ Do not lie flat or bettine ■ Raise the head of your bed ■ Avoid heartburn-causing foods such as rich, spley, fatly or fried foods, chocoftae, caffeine, alcohd, and certain fruits and vegetables ≡Est stowly and avoid big mests ≡ fir overweight, loss weight ■ Duit smoking Tips for Managing Heartburn

drinking certain foods and beverages.

This product is not manufactured or distributed by MCNEIL CONSUMER PHARMACEUTICALS, distributor of Pepcid AC® Original Strength. 'he Supermarket Low Price Leader® 300-824-1706 www.wincofoods.com ments & Questions SATISFACTION

SEE END PANEL FOR BATCH NUMBER AND EXPIRATION DATE

ISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

OR

Other information

Other information

■ store at S0° to S5° C (68° to 77° F)

■ protect from moisture

■ read the directions and warnings before use

■ keep the carton, it contains important information,

Inactive ingredients colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, propellatinised starch, talc, titanium dioxide, incrocrystalline cellulose, polyethylene glycol 400, pregelatinised starch, talc, titanium dioxide

Questions? or to report an adverse event call 800-824-1706 Monday - Friday 9am - 4pm MST

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Outestions? Or to report an adverse event call 800-824-1706 Monday - Friday 9am - 4pm MST

Outestions?

## PRINCIPAL DISPLAY PANEL - 20 mg Blister Pack Carton

\*Compare to the active ingredient in PEPCID AC® Maximum Strength

WinCo™
FOODS
MAXIMUM STRENGTH
Acid Controller

FAMOTIDINE TABLETS, USP 20 mg/ ACID REDUCER JUST ONE TABLET Prevents & Relieves Heartburn Due to Acid Indigestion

25 Tablets



25 TABLETS

\*Compare to the active ingredient in PEPCID AC® Maximum Strength

## WinCo

MAXIMUM STRENGTH **Acid Controller** 

## **FAMOTIDINE TABLETS,** USP 20 mg/ ACID REDUCER

JUST ONE TABLET Prevents & Relieves Heartburn Due to Acid Indigestion

SEE END PANEL FOR BATCH NUMBER AND EXPIRATION DATE.

This product is not manufactured or distributed by MCNEIL CONSUMER PHARMACEUTICALS, distributor of PEPCID AC® Maximum Strength.

The Supermarket Low Price Leader®

SATISFACTION

800-824-1706 www.wincofoods.com

Comments & Questions?

TAMPER EVIDENT: DO NOT USE IF THE CARTON OR

FOIL UNDER CAP IS OPEN OR TORN

■ Do not le flat or bend over after eating ■ Do not wear tight-fitting dothing around the stomach ■ Do not be the flat or bend over after eating ■ Do not wear tight-fitting dothing around the stomach ■ Do not eat before bettine ■ Risase the head of your bed ■ Avoid hearbunn-ausing loods such as rich: Specy, faity or fried foods, chocobe, cartiene, alcohd, and estain fruits and vegetables ■ Est slowly and avoid big meals ■ If overveight, lose weight ■ Guit smoking

/arnish Free

drinking certain foods and beverages.

DUST ONE TABLET prevents and relieves heartburn due to acid indigestion brought on by eating and Questions? or to report an adverse event call 800-824-1706 Monday - Friday 9am - 4pm MST

starch, talc, titanium dioxide

magnesium stearate, microcrystaline celulose, polyethylene glycol 400, pregelatinized Inactive ingredients colloidal allicon dioxide, hydroxypropyl cellulose, hypromellose,

- keep the carton. It contains important information.
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Other information

Drug Facts (continued)

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- do not use more than 2 tablets in 24 nours quuying beverages that cause heartburn to 60 minutes before eating food or
- with a glass of water at any time from 10 ■ to prevent symptoms, swallow 1 tablet with a glass of water. Do not chew
  - to relieve symptoms, swallow 1 tablet adults and children 12 years and over:

#### Directions

Control Center right away (1-800-222-1222). overdose, get medical help or contact a Polson Keep out of reach of children, in case of professional before use.

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14 days

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to famotidine or other acid reducers Allergy alert: Do not use if you are allergic Warnings

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- by eating or drinking certain food and indigestion and sour stomach brought on
- prevents heartburn associated with acid indigestion and sour stomach
- relieves heartburn associated with acid





### FAMOTIDINE - ACID CONTROLLER

famotidine tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-242

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthFAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)FAMOTIDINE10 mg

# Inactive Ingredients

Ingredient Name Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

HYDROXYPROPYL CELLULOSE (1200000 MW) (UNII: RFW2ET671P)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

FERRIC OXIDE RED (UNII: 1K09F3G675)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

STARCH, CORN (UNII: O8232NY3SJ)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

#### **Product Characteristics**

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

Contains

## **Packaging**

1 NDC:67091-242-30 30 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/08/2015

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090283	05/01/2012	

## **FAMOTIDINE - ACID CONTROLLER**

famotidine tablet, film coated

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67091-241

Route of Administration ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMO TIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
HYDROXYPROPYL CELLULOSE (1200000 MW) (UNII: RFW2ET671P)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6130)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
STARCH, CORN (UNII: O8232NY3SJ)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

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

l	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
ı	1 NDC:67091-241-25	25 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 8/20 15	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090283	05/01/2012	

## Labeler - WinCo Foods, LLC (056098817)

## Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment			
Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	MANUFACTURE(67091-241, 67091-242)

Revised: 9/2018 WinCo Foods, LLC