

**ZANTAC 360- famotidine tablet, film coated**  
**Chattem, Inc.**

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**Zantac 360**

***Zantac 360<sup>o</sup>***

***Famotidine Tablets 10 mg / Acid Reducer***

***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 right away. (1-800-222-1222)

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

***Inactive ingredients***

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

## **Questions or comments**

call **1-800-633-1610** or visit **www.zantacotc.com**

## **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

## **Zantac 360<sup>o</sup>**

### **Famotidine Tablets 20 mg / Acid Reducer**

#### **Drug Facts**

#### **Active ingredient (in each tablet)**

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

***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
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F)

- protect from moisture

### ***Inactive ingredients***

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

### ***Questions or comments?***

call **1-800-633-1610** or visit **[www.zantacotc.com](http://www.zantacotc.com)**

### **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

### **PRINCIPAL DISPLAY PANEL**

Zantac  
Famotidine Tablets USP 10 mg / Acid Reducer  
360  
30 Tablets



**PRINCIPAL DISPLAY PANEL**

Zantac  
 Famotidine Tablets USP 20 mg / Acid Reducer  
 360  
 100 Tablets



# ZANTAC 360

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0360
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROXYPROPYL CELLULOSE (160000 WAMW) (UNII: RFW2ET671P)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	

## 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:41167-0360-2	1 in 1 CARTON	04/12/2021	
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	04/12/2021	

## ZANTAC 360

famotidine tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0361
Route of Administration	ORAL		



**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>FAMOTIDINE</b> (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYDROXYPROPYL CELLULOSE (1600000 WAMW)</b> (UNII: RFW2ET671P)	
<b>HYPROMELLOSE 2910 (5 MPA.S)</b> (UNII: R75537T0T4)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND (Square shaped Biconvex)	<b>Size</b>	5mm
<b>Flavor</b>		<b>Imprint Code</b>	CC;59
<b>Contains</b>			

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:41167-0361-0	1 in 1 CARTON	04/12/2021	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-0361-2	1 in 1 CARTON	04/12/2021	
2		25 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41167-0361-4	1 in 1 CARTON	04/12/2021	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:41167-0361-9	2 in 1 CELLO PACK	04/12/2021	
4		70 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:41167-0361-6	1 in 1 CARTON	04/12/2021	
5		90 in 1 BOTTLE; Type 0: Not a Combination Product		

6	NDC:41167-0361-8	1 in 1 CARTON	04/12/2021	
6		100 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:41167-0361-1	1 in 1 CARTON	04/12/2021	
7		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206531	04/12/2021	

**Labeler** - Chattem, Inc. (003336013)

Revised: 5/2022

Chattem, Inc.