

**ZANTAC 360 1 PER BLISTER 6 BLISTERS- famotidine tablet, film coated**  
**JC World Bell Wholesale Co., Inc.**

-----  
**Zantac 360, 1 tablet per blister, 6 blisters**

***Drug Facts***

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

Famotidine USP 20mg

***Purpose***

Acid reducer

***Uses***

- relieves heartburn associated with acid indigestion and sour stomach
- prevent 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 or 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 **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°F-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)**

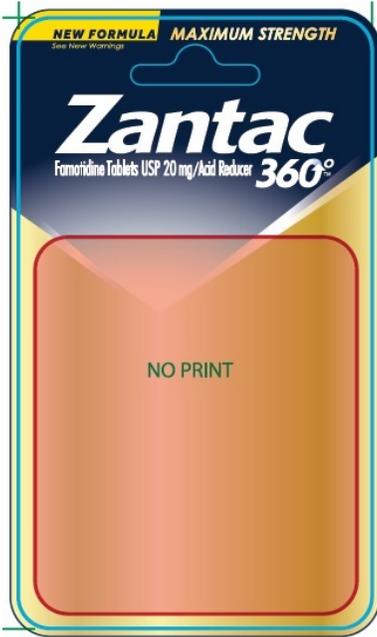
**Package Labeling:**



Drug Facts	Drug Facts (continued)
<p><b>Active ingredient (in each tablet)</b> Famotidine USP 20 mg</p> <p><b>Purpose</b> Acid reducer</p> <p><b>Uses</b>  <ul style="list-style-type: none"> <li>relieves heartburn associated with acid indigestion and sour stomach</li> <li>prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages</li> </ul> </p> <p><b>Warnings</b>  <ul style="list-style-type: none"> <li><b>Allergy alert:</b> Do not use if you are allergic to famotidine or other acid reducers</li> </ul> </p> <p><b>Do not use</b>  <ul style="list-style-type: none"> <li>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.</li> <li>with other acid reducers</li> </ul> </p> <p><b>Ask a doctor before use if you have</b>  <ul style="list-style-type: none"> <li>had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>heartburn with lipheadness, swelling, or dizziness</li> <li>chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadness</li> <li>troubling chest pain</li> <li>frequent wheezing, particularly with heartburn</li> <li>unexplained weight loss</li> <li>nausea or vomiting</li> <li>stomach pain</li> <li>kidney disease</li> </ul> </p> <p><b>Ask a doctor or pharmacist before use if you are taking a prescription drug.</b> Acid reducers may interact with certain prescription drugs.</p> <p><b>Stop use and ask a doctor if</b>  <ul style="list-style-type: none"> <li>your heartburn continues or worsens</li> </ul> </p>	<p>you need to take this product for more than 14 days</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p><b>Directions</b>  <ul style="list-style-type: none"> <li>adults and children 12 years and over</li> <li>to relieve symptoms, swallow 1 tablet with a glass of water. Do not chew.</li> <li>to prevent symptoms, swallow 1 tablet with a glass of water at any time from 30 to 60 minutes before eating food or drinking beverages that cause heartburn</li> <li>do not use more than 2 tablets in 24 hours</li> <li>children under 12 years: ask a doctor</li> </ul> </p> <p><b>Other information</b>  <ul style="list-style-type: none"> <li>read the directions and warnings before use</li> <li>keep the carton. It contains important information.</li> <li>store at 20°C - 25°C (68°F - 77°F)</li> <li>protect from moisture</li> </ul> </p> <p><b>Inactive ingredients</b>            cornstarch, croscarmellose, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide, sodium starch glycolate, talc, titanium dioxide, yellow iron oxide         </p> <p><b>Questions or comments?</b> call 1-800-633-1610 or visit <a href="http://www.zantac360.com">www.zantac360.com</a></p>
<p><b>Tips for Managing Heartburn</b></p> <ul style="list-style-type: none"> <li>Do not lie flat or bend over after eating</li> <li>Do not wear tight-fitting clothing around the stomach</li> <li>Do not eat before bedtime</li> <li>Raise the head of your bed</li> <li>Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol, and certain fruits and vegetables</li> <li>Eat slowly and avoid big meals</li> <li>If overweight, lose weight</li> <li>Quit smoking</li> </ul> <p><b>Made in India.</b></p> <p><b>JUST ONE TABLET</b> prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.</p> <p>Do not use if the individual blister unit is open or torn.</p>	<p><b>Lot:</b></p> <p><b>EXP:</b></p> <p></p> <p>0 731946 011811</p>

BACK

FRONT



FRONT CARD



**Now with Famotidine**

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b>      <b>Purpose</b>  Famotidine USP 20 mg.....Acid reducer</p> <p><b>Uses</b>  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><b>Warnings</b>  <b>Allergy alert:</b> Do not use if you are allergic to famotidine or other acid reducers</p> <p><b>Do not use</b>  ■ 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</p> <p><b>Ask a doctor before use if you have</b>  ■ had heartburn over 3 months. This may be a sign of a more serious condition, ■ heartburn with <b>lightheadedness, sweating, or dizziness</b> ■ 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</p> <p><b>Ask a doctor or pharmacist before use if you are taking a prescription drug.</b> Acid reducers may interact with certain prescription drugs.</p> <p><b>Stop use and ask a doctor if</b>  ■ your heartburn continues or worsens</p> <p><b>Do not use if the individual blister unit is open or torn.</b></p> <p><b>Tips for Managing Heartburn</b>  - 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</p> <p style="text-align: right;"><b>Made in India.</b></p> <p><b>JUST ONE TABLET</b>  prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.</p> <p>Product repackaged and distributed with permission of the manufacturer by: JC World Bell Wholesale Company, Inc. Hackensack, NJ 07601</p>		<p><b>Drug Facts (continued)</b></p> <p>■ you need to take this product for more than 14 days</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p><b>Directions</b>  ■ 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><b>Other information</b>  ■ read the directions and warnings before use  ■ keep the carton. It contains important information.  ■ store at 20°C-25°C (68°F-77°F)  ■ protect from moisture</p> <p><b>Inactive ingredients</b>  carnauba wax, corn starch, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, red iron oxide, sodium starch glycolate, talc, titanium dioxide, yellow iron oxide</p> <p><b>Questions or comments?</b> call 1-800-633-1610 or visit <a href="http://www.zantacotc.com">www.zantacotc.com</a></p> <p>Lot:  EXP:</p>  <p>0 731946 011804</p>	
--	--	---	--

**ZANTAC 360 1 PER BLISTER 6 BLISTERS**

famotidine tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50269-155(NDC:41167-0361)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

### Product Characteristics

Color	yellow	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	CC;59
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-155-01	6 in 1 BOX	10/01/2021	
1		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	10/01/2021	

**Labeler** - JC World Bell Wholesale Co., Inc. (805257581)

Revised: 8/2022

JC World Bell Wholesale Co., Inc.