**ZANTAC 360- famotidine tablet, film coated**
**Navajo Manufacturing Company Inc.**

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**Zantac 360**

***Zantac 360º***

***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 **15to 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

## PRINCIPAL DISPLAY PANEL


## ZANTAC 360

famotidine tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:67751-214(NDC:41167-0361) |
| **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) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |

| | |
|---|---|
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **HYDROXYPROPYL CELLULOSE (1600000 WAMW)** (UNII: RFW2ET671P) | |
| **HYPROMELLOSE 2910 (5 MPA.S)** (UNII: R75537T0T4) | |
| **SODIUM STARCH GLYCOLATE TYPE A CORN** (UNII: AG9B65PV6B) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | ROUND (Square shaped Biconvex) | **Size** | 5mm |
| **Flavor** | | **Imprint Code** | CC;59 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:67751-214-01 | 1 in 1 CARTON | 08/01/2022 | |
| **1** | | 1 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:67751-214-02 | 2 in 1 CARTON | 08/01/2022 | |
| **2** | | 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 | 08/01/2022 | |

## Labeler - Navajo Manufacturing Company Inc. (091917799)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Navajo Manufacturing Company Inc. | | 136941411 | relabel(67751-214) , repack(67751-214) |