

**RANITIDINE- ranitidine tablet, coated**  
**Thirty Madison Inc**

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**Drug Facts**

**Active ingredient (in each tablet)**

Ranitidine 150 mg (as ranitidine hydrochloride USP, 168 mg)

**Purpose**

Acid reducer

**Use(s)**

- 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 foods and beverages

**Warnings**

**Allergy alert:** Do not use if you are allergic to ranitidine 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
- if you have kidney disease, except under the advice and supervision of a doctor

**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

**Stop use and ask 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.

## Directions

- adults and children 12 years and over:
  - to **relieve** symptoms, swallow 1 tablet with a glass of water
  - to **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn
  - can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- children under 12 years: ask a doctor

## Other information

- do not use if printed foil under bottle cap is open or torn
- store at 20°-25°C (68°-77°F)
- avoid excessive heat or humidity
- protect from light
- this product is sodium and sugar free

## Inactive ingredients

FD&C red #40 aluminum lake, hypromellose, iron oxide black, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

## Questions?

Call **1-888-375-3784**

## Bottle Label

**evens**

Maximum Strength  
Ranitidine Tablets  
USP, 150mg  
Acid Reducer

Prevents & relieves heartburn associated with acid indigestion and sour stomach  
95 Tablets (95 doses)

**TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP PRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING**

**IMPORTANT:** This label does not contain full product information. See carton for complete information. Read the directions, consumer information leaflet and warnings before use. Retain carton and leaflet for reference.

**Active ingredient (in each tablet):** Ranitidine 150 mg (as ranitidine hydrochloride USP, 168 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 foods and beverages

**Warnings:**  
**Allergy alert:** Do not use if you are allergic to ranitidine 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 ■ if you have kidney disease, except under the advice and supervision of a doctor

**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

**Stop use and ask a doctor if:** ■ your heartburn worsens or 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.

**Directions:** ■ adults and children 12 years and over:  
■ to relieve symptoms, swallow 1 tablet with a glass of water  
■ to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn ■ can be used up to twice daily (do not take more than 2 tablets in 24 hours)  
■ children under 12 years: ask a doctor

**Questions?** Call 1-888-375-3784

Distributed by Thirty Madison, Inc.  
New York, NY 10016

150076039

LOT  
EXP

# Carton label



## RANITIDINE

ranitidine tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71713-203(NDC:55111-404)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Ranitidine Hydrochloride</b> (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	150 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>magnesium stearate</b> (UNII: 70097M6I30)	
<b>cellulose, microcrystalline</b> (UNII: OP1R32D61U)	

**POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ)

**titanium dioxide** (UNII: 15FIX9V2JP)

### Product Characteristics

<b>Color</b>	PINK	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	R150
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71713-203-05	1 in 1 CARTON	05/31/2019	09/30/2019
1		95 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:71713-203-02	1 in 1 CARTON	05/31/2019	09/30/2019
2		24 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	ANDA078192	05/31/2019	

**Labeler** - Thirty Madison Inc (080774087)

Revised: 9/2019

Thirty Madison Inc