

HERATBURN RELIEF- ranitidine tablet, coated
The Kroger Co.

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.(1-800-222-1222)

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 **1-800-632-6900**

Consumer Information

What you should know about

MAXIMUM STRENGTH

Ranitidine Tablets USP, 150 mg

(Please read all of this information before taking MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg. Save this leaflet for future reference.)

What are MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg?

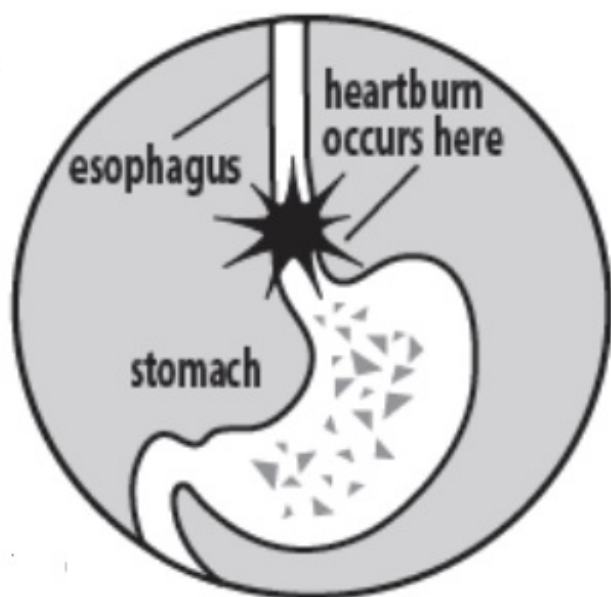
- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg contains 150 mg of ranitidine (as ranitidine hydrochloride USP, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

Excellent Safety Record

- The ingredient in MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg has been taken safely with many frequently prescribed medications.
- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg are sodium and sugar free.

What symptoms does MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg relieve and prevent?

- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg relieve and prevent heartburn associated with acid indigestion and sour stomach. Eating or drinking certain foods or beverages, and even lying down to sleep, can cause heartburn associated with acid indigestion and sour stomach. It is normal to the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause burning pain and discomfort.



How should I take MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg?

- 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. This medicine can be used up to twice daily (up to 2 tablets in 24 hours).
- Do not chew tablet.
- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg should not be given to children under 12 years old unless directed by a doctor.
- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers.

How does MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg work?

- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg reduce the production of stomach acid. This is what make MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

Tips for managing heartburn

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

When should I see a doctor?

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
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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.

Questions? Call 1-888-375-3784

BOTTLES: Bottle is sealed with printed foil under cap. Do not use if printed foil is open or torn.

BLISTERS: Do not use if the individual blister unit is open or torn.

Consumer Information

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION. IMPORTANT:

Read the directions, consumer information leaflet and warnings before use. Keep the carton. It contains important information.

Container Carton Label:





HERATBURN RELIEF

ranitidine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-505(NDC:55111-404)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
magnesium stearate (UNII: 70097M6I30)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	R150
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-505-34	1 in 1 CARTON	04/24/2011	09/30/2019
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:30142-505-50	1 in 1 CARTON	04/24/2011	09/30/2019
2		50 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	04/24/2011	

Labeler - The Kroger Co. (006999528)

Revised: 9/2019

The Kroger Co.