

COOL MINT ACID REDUCER- ranitidine tablet, film coated
Rite Aid Corporation

Rite Aid Corporation Cool Mint Acid Reducer Drug Facts

Active ingredient (in each tablet)

Ranitidine 150 mg (as ranitidine hydrochloride 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 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)
- do not chew tablet
- 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
- this product is sodium and sugar free

Inactive ingredients

FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, natural and artificial mint flavor, sucralose, titanium dioxide, triacetin

Questions or comments?

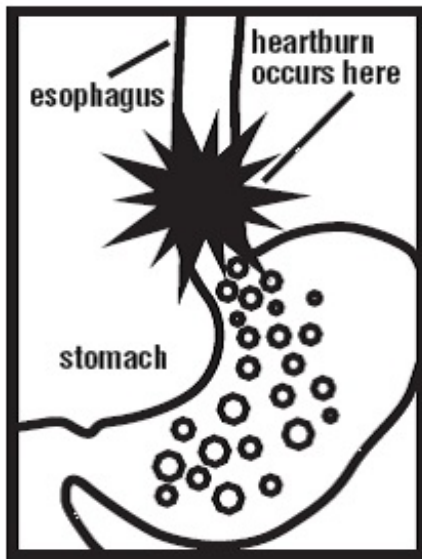
1-800-719-9260

Consumer Information**What you should know about MAXIMUM STRENGTH Ranitidine Tablets, 150 mg Acid Reducer Cool Mint Tablets**

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

What are MAXIMUM STRENGTH Ranitidine Tablets, 150 mg?

- MAXIMUM STRENGTH Ranitidine Tablets, 150 mg contain 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.
- When swallowed, MAXIMUM STRENGTH Ranitidine Tablets, 150 mg release a cooling sensation in the mouth and throat.



Excellent Safety Record

- The ingredient in MAXIMUM STRENGTH Ranitidine Tablets, 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, 150 mg has been taken safely with many frequently prescribed medications
- MAXIMUM STRENGTH Ranitidine Tablets, 150 mg are sodium and sugar free.

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

- MAXIMUM STRENGTH Ranitidine Tablets, 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 for 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, 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, 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 do MAXIMUM STRENGTH Ranitidine Tablets, 150 mg work?

MAXIMUM STRENGTH Ranitidine Tablets, 150 mg reduce the production of stomach acid. This is what makes MAXIMUM STRENGTH Ranitidine Tablets, 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
- nausea or vomiting
- stomach pain
- **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 healthcare 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).

Questions or comments? 1-800-719-9260

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.

Distributed By

Perrigo®

Allegan, MI 49010

: 950B5 00 J2

Package/Label Principal Display Panel

Compare to the active ingredient of Zantac 150® Cool Mint Tablets

MAXIMUM STRENGTH

cool mint acid reducer

ranitidine tablets USP, 150 mg • acid reducer

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

cool mint tablets

ACTUAL SIZE

Releases a Cooling Sensation in Mouth & Throat

sugar free

24 COOL MINT TABLETS (24 DOSES)



COOL MINT ACID REDUCER

ranitidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0950
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 BLUE NO. 1 (UNII: HBR47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	BLUE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	L950
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0950-1	1 in 1 CARTON	12/07/2011	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:11822-0950-0	1 in 1 CARTON	12/07/2011	
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	ANDA091429	12/07/2011	

Labeler - Rite Aid Corporation (014578892)