# LEADER RANITIDINE- ranitidine tablet, film coated Cardinal Health

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# Cardinal Health Ranitidine Tablets 150 mg 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)
- children under 12 years: ask a doctor

#### Other information

- do not use if individual blister unit 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**

D&C yellow #10 aluminum lake, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, 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**

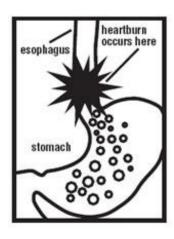
(Please read all of this information before taking MAXIMUM STRENGTH Ranitidine Tablets, 150 mg. Save this leaflet for future reference.)

## 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.

# **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.
- 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 (do not take more than 2 tablets in 24 hours).
- 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

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# Package/Label Principal Display Panel

Maximum Strength

Acid Control

Ranitidine Tablets, 150 mg | Acid Reducer

COMPARE TO ZANTAC 150® active ingredient

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

100% Money Back Guarantee

24 TABLETS (24 Doses)

**Actual Size** 



Return to place of purchase if not satisfied.



#### LEADER RANITIDINE

ranitidine tablet, film coated

#### **Product Information**

Product Type HUMAN OTC DRUG NDC:70000-0377 Item Code (Source)

Route of Administration ORAL

### Active Ingredient/Active Moiety

**Ingredient Name** Basis of Strength Strength 150 mg

RANITIDINE HYDRO CHLO RIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7) RANITIDINE

#### **Inactive Ingredients**

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DOK)	

FD&C RED NO.40 (UNII: WZB9127XOA)

HYPROMELLOSES (UNII: 3NXW29V3WO)

MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics				
Color	BROWN (Pinkish)	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	L852	
Contains				

Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1 NDC:70000-0377-1	24 in 1 CARTON	08/03/2018		
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	ANDA091429	08/03/2018		

# Labeler - Cardinal Health (097537435)

Revised: 8/2018 Cardinal Health