RANITIDINE- ranitidine hydrochloride tablet, film coated
Liberty Pharmaceuticals, Inc.

Drug Facts

Active Ingredient(s)

Ranitidine 150 mg (as ranitidine hydrochloride 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 certain foods and beverages

Warnings

Allergy alert: Do not use if you are allergic to ranitidine or any other acid reducers.

Do not use

- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor
- 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

Ask a doctor before use if you have

- nausea or vomiting
- stomach pain
- unexplained weight loss
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- 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

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

Pregnancy/Breastfeeding

If pregnant or breastfeeding, 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)
- do not chew tablet
- children under 12 years: ask a doctor

Other Information

- do not use if bottle seal is open or torn
- store at 20° to 25°C (68° to 77°F)
- protect from light
- this product is sodium and sugar free

Inactive Ingredients

carnauba wax, colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, titanium dioxide, vanillin, red and yellow ferric oxide.

Questions or Comments?

Call **1-800-706-5575** (Monday to Friday 8:30 a.m. – 5:00 p.m. Eastern Standard Time)

Consumer Information

What you should know about

MAXIMUM STRENGTH

Ranitidine Tablets USP, 150 mg / Acid Reducer

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

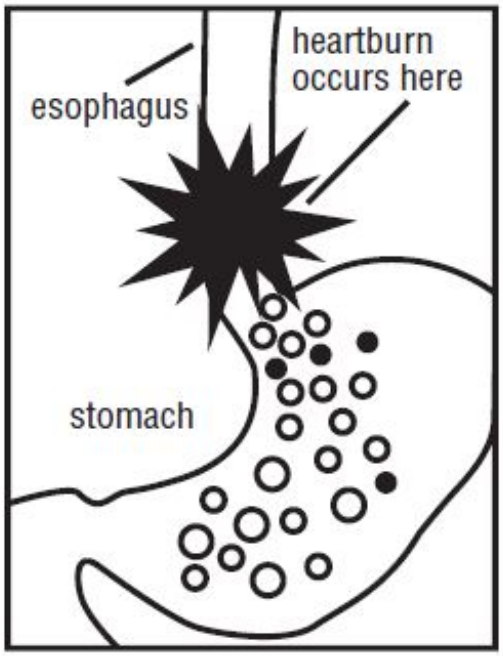
What are MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg?

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

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

MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg relieves and prevents 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.



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.

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

MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg should not be given to children under 12 years old unless directed by a doctor.

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

MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg reduces the production of stomach acid. This is what makes 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
- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers

When should I see a doctor?

- **Do not use**
  - with other acid reducers
  - if you have kidney disease, except under the advice and supervision of a doctor
  - 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.

- **Ask a doctor before use if you have**
  - nausea or vomiting
  - stomach pain
  - unexplained weight loss
  - frequent **chest pain**
  - frequent wheezing, particularly with heartburn
  - 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
- **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 or Comments?

Call **1-800-706-5575** (Monday to Friday, 8:30 am – 5:00 pm Eastern Standard Time)

Manufactured by:	Manufactured for:
Apotex Inc.	Apotex Corp.
Toronto, Ontario	Weston, FL
Canada M9L 1T9	33326

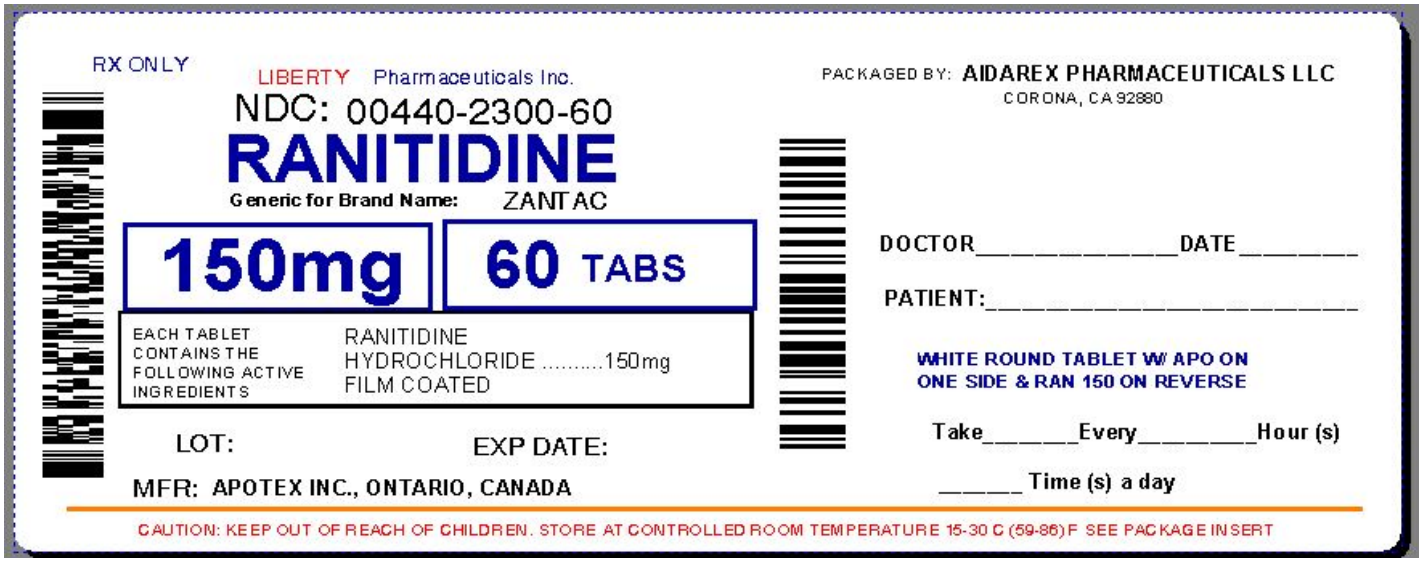
Repackaged By :
Aidarex Pharmaceuticals LLC,
Corona, CA 92880

Principal Display Panel

OTC Medicine

Maximum Strength

Rantidine Tablets USP, 150 mg



RANITIDINE

ranitidine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0440-2300(NDC:60505-2880)
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**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
VANILLIN (UNII: CHI530446X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics			
Color	PINK	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0440-2300-60	60 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200172	07/15/2013	

Labeler - Liberty Pharmaceuticals, Inc. (012568840)

Revised: 9/2013 Liberty Pharmaceuticals, Inc.