

**RANITIDINE- ranitidine hydrochloride tablet, film coated**  
**Apotex Corp.**

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***Drug Facts***

***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 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

## 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 broken or torn
- store at 20°C to 25°C (68°F to 77°F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

## Inactive ingredients

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

## Questions?

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

## Principal Display Panel

Maximum Strength

Ranitidine Tablets USP, 150 mg - Bottle Label - 10,000 Tablets

Acid Reducer

Prevents & Relieves Heartburn

Associated with Acid Indigestion & Sour Stomach

Distributed by: Apotex Corp. Weston, Florida 33326, USA

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet) ..... Purpose</b> Ranitidine 150 mg (as ranitidine hydrochloride 168 mg).... Acid reducer</p> <p><b>Uses</b></p> <ul style="list-style-type: none"><li>■ relieves heartburn associated with acid indigestion and sour stomach</li><li>■ prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages</li></ul> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> Do not use if you are allergic to ranitidine or other acid reducers</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"><li>■ 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</li><li>■ with other acid reducers</li><li>■ if you have kidney disease, except under the advice and supervision of a doctor</li></ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"><li>■ had heartburn over 3 months. This may be a sign of a more serious condition</li><li>■ heartburn with <b>lightheadedness, sweating or dizziness</b></li><li>■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or <b>lightheadedness</b></li><li>■ frequent <b>chest pain</b> ■ frequent wheezing, particularly with heartburn</li><li>■ unexplained weight loss ■ nausea or vomiting ■ stomach pain</li></ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"><li>■ your heartburn continues or worsens</li><li>■ you need to take this product for more than 14 days</li></ul>	<p>NDC 60505-2880-7</p> <p><b>MAXIMUM STRENGTH</b></p> <p><b>Ranitidine</b></p> <p><b>Tablets, USP 150 mg</b></p> <p><b>Acid Reducer</b></p> <p><b>PREVENTS &amp; RELIEVES</b></p> <p><b>HEARTBURN</b></p> <p><b>associated with acid</b></p> <p><b>indigestion and sour stomach</b></p> <p><b>10,000</b></p> <p><b>TABLETS</b></p> <p><b>FOR REPACKAGING ONLY</b></p> <p>Read the directions, consumer information leaflet and warnings before use. It contains important information.</p> <p><b>APOTEX CORP.</b></p>	<p><b>Drug Facts (continued)</b></p> <p>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.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>■ adults and children 12 years and over:<ul style="list-style-type: none"><li>■ to <b>relieve</b> symptoms, swallow 1 tablet with a glass of water</li><li>■ to <b>prevent</b> symptoms, swallow 1 tablet with a glass of water <b>30 to 60 minutes before</b> eating food or drinking beverages that cause heartburn</li><li>■ can be used up to twice daily (do not take more than 2 tablets in 24 hours)</li></ul></li><li>■ children under 12 years: ask a doctor</li></ul> <p><b>Other information</b></p> <ul style="list-style-type: none"><li>■ do not use if printed foil under bottle cap is broken or torn</li><li>■ store at 20°C to 25°C (68°F to 77°F)</li><li>■ avoid excessive heat or humidity</li><li>■ this product is sodium and sugar free</li></ul> <p><b>Inactive ingredients</b></p> <p>carnauba wax, colloidal silicon dioxide, ferric oxide red, ferric oxide yellow, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, titanium dioxide and vanillin</p> <p><b>Questions or Comments?</b></p> <p>Call 1-800-706-5575 (Monday to Friday 8:30 a.m. – 5:00 p.m. Eastern Standard Time)</p>	<p>MANUFACTURED BY: APOTEX INC., TORONTO CANADA, M9L 1T9 MANUFACTURED FOR: APOTEX CORP. WESTON, FLORIDA, 33326</p> <p>3 60505 28807 6</p>
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# RANITIDINE

ranitidine hydrochloride tablet, film coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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: CH530446X)	
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:60505-2880-7	10000 in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2013	
2	NDC:60505-2880-0	3 in 1 CARTON	07/15/2013	
2		8 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	ANDA200172	07/15/2013	

**Labeler** - Apotex Corp. (845263701)

**Registrant** - Apotex Inc. (209429182)

**Establishment**

Name	Address	ID/FEI	Business Operations
Apotex Inc		209429182	manufacture(60505-2880) , analysis(60505-2880)

Revised: 6/2017

Apotex Corp.