

RANITIDINE- ranitidine hydrochloride tablet, film coated
Apotex Corp.

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 any 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.

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, polyethylene glycol, titanium dioxide and vanillin

Questions or Comments?

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 10,000 ct bottle

Acid Reducer

Prevents & Relieves

Heartburn Associated with Acid Indigestion & Sour Stomach

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

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Ranitidine 150 mg (as ranitidine hydrochloride 168 mg).... Acid reducer</p> <p>Uses</p> <ul style="list-style-type: none">■ 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 <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers</p> <p>Do not use</p> <ul style="list-style-type: none">■ 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 <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none">■ 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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none">■ your heartburn continues or worsens■ you need to take this product for more than 14 days	<p>NDC 60505-2880-7</p> <p>MAXIMUM STRENGTH</p> <p>Ranitidine</p> <p>Tablets, USP 150 mg</p> <p>Acid Reducer</p> <p>PREVENTS & RELIEVES</p> <p>HEARTBURN</p> <p>associated with acid</p> <p>indigestion and sour stomach</p> <p>10,000</p> <p>TABLETS</p> <p>FOR REPACKAGING ONLY</p> <p>Read the directions, consumer information leaflet and warnings before use. It contains important information.</p> <p>APOTEX CORP.</p>	<p>Drug Facts (continued)</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>Directions</p> <ul style="list-style-type: none">■ adults and children 12 years and over:<ul style="list-style-type: none">■ 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 <p>Other information</p> <ul style="list-style-type: none">■ 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 <p>Inactive ingredients</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>Questions or Comments?</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>60505-28807 6</p> <p>3</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	

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: 10/2016

Apotex Corp.