

RANITIDINE- ranitidine hydrochloride tablet, film coated
Aphena Pharma Solutions - Tennessee, LLC

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)

Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

Count	150mg
180	43353-952-80
1000	43353-952-71

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20160602DH

Principal Display Panel

Maximum Strength

Ranitidine Tablets USP, 150 mg 180 & 1000 ct bottle

Acid Reducer

Prevents & Relieves

Heartburn Associated with Acid Indigestion & Sour Stomach

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

PRINCIPAL DISPLAY PANEL - 150mg

NDC 43353-952 - **Ranitidine HCl** 150mg - Rx Only

NDC # 43353-0952-80

Ranitidine HCl
150mg 180 Tablets

Store between 20-25 degrees C (68-77 degrees F).
See USP Controlled Room Temperature.
Dispense in a tight light-resistant container as defined by USP.
Keep this and all drugs out of the reach of children.

Mfg. By: Apotex Inc.
Toronto, Canada
Repackaged by Aphena Pharma
Cookeville, TN 38506

Batch:
Exp:
Lot:

RX Only

Ranitidine HCl 150mg 180 Tablets

RANITIDINE

ranitidine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43353-952(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:43353-952-80	180 in 1 BOTTLE; Type 0: Not a Combination Product	06/26/2014	
2	NDC:43353-952-71	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/28/2014	

Marketing Information

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

Labeler - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(43353-952)

Revised: 6/2016

Aphenia Pharma Solutions - Tennessee, LLC