MAXIMUM STRENGTH RANITIDINE - ranitidine tablet
Aurohealth LLC

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

Active ingredient (in each tablet)

Ranitidine 150 mg (as ranitidine hydrochloride USP 167.414 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

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
- kidney disease

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Acid reducers may interact with certain prescription drugs.

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 (1-800-222-1222) 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

- **TAMPER EVIDENT: Do Not Use If The Carton Or Printed Foil Under Cap Is Open or Torn**
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat or humidity
- this product is sugar free
- USP Dissolution Test Pending.

Inactive ingredients

croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, titanium dioxide, and triacetin

Questions?

call **1-855-274-4122**

Read the directions and warnings before use. Keep the carton. It contains important information including tips for managing heartburn.

Distributed by:
AUROHEALTH LLC
2572 Brunswick Pike
Lawrenceville, NJ 08648

Made in India

Code: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 150 mg Container (24 Tablets Bottle)

AUROHEALTH

NDC 58602-734-07
MAXIMUM STRENGTH
Ranitidine Tablets USP,
150 mg
ACID REDUCER
PREVENTS & RELIEVES
HEARTBURN *associated with*
acid indigestion and sour stomach
24 TABLETS
(24 DOSES)

Labeling Format Information:	
Font type :	Helvetica Condensed
Barline	NA
Drug facts :	NA
Drug facts (continued):	NA
Header :	6 pt
Subheader :	4.5 pt
Leading :	0.5 pt
Body text :	4.5 pt
Bullets :	4 pt

A/s: 107.5 x 28.5 mm

* Lot: XXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 150 mg Container Carton (24's Tablets)

AUROHEALTH

NDC 58602-734-07
***Compare to the active ingredient in Zantac 150®**
MAXIMUM STRENGTH
Ranitidine
Tablets USP,
150 mg
ACID REDUCER
PREVENTS & RELIEVES
HEARTBURN *associated with*
acid indigestion and sour stomach
24 TABLETS
(24 DOSES)

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 150 mg Blister Carton (8's (1 x 8) Tablets)

AUROHEALTH

NDC 58602-734-79
***Compare to the active ingredient in Zantac 150®**
MAXIMUM STRENGTH
Ranitidine Tablets USP, 150 mg
ACID REDUCER
PREVENTS & RELIEVES HEARTBURN *associated with acid indigestion and sour stomach*
8 TABLETS (8 DOSES)

MAXIMUM STRENGTH RANITIDINE

ranitidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58602-734
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE (White to Off-white)	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	K;43
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-734-02	1 in 1 CARTON	04/24/2019	
1		8 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-734-07	1 in 1 CARTON	11/13/2017	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-734-17	1 in 1 CARTON	11/13/2017	
3		45 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-734-14	1 in 1 CARTON	11/13/2017	
4		50 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-734-16	1 in 1 CARTON	11/13/2017	
5		65 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-734-50	1 in 1 CARTON	11/13/2017	
6		85 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-734-20	1 in 1 CARTON	11/13/2017	
7		95 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-734-40	1 in 1 CARTON	11/13/2017	
8		500 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:58602-734-79	1 in 1 CARTON	11/12/2019	
9		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	ANDA207578	11/13/2017	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-734) , MANUFACTURE(58602-734)

Revised: 11/2019 Aurohealth LLC