

RANITIDINE - ranitidine tablet, film coated
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

Drug Facts

Active ingredient (in each tablet)

Ranitidine 75 mg (as ranitidine hydrochloride USP 83.707 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)
 - do not chew tablet
- 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.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 75 mg (60 Tablets Bottle)

AUROHEALTH

NDC 58602-733-15

Regular Strength

**Ranitidine
Tablets USP,
75 mg**

**ACID
REDUCER**

**PREVENTS & RELIEVES
HEARTBURN** associated with acid
indigestion and sour stomach

60 TABLETS (60 DOSES)



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

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 75 mg (60 Tablets Container Carton)

AUROHEALTH

NDC 58602-733-15

***Compare to the active
ingredient in Zantac 75®**

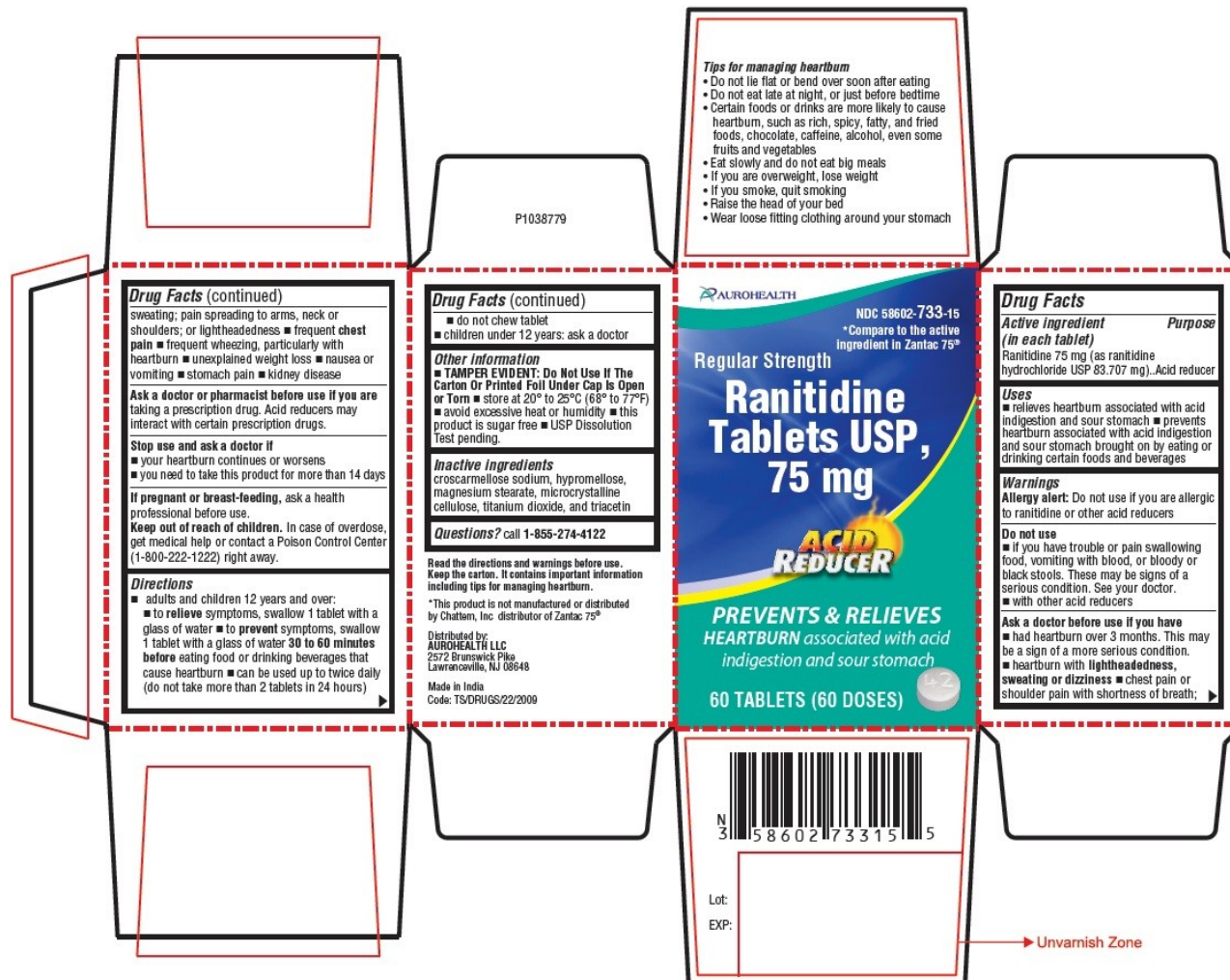
Regular Strength

**Ranitidine
Tablets USP,
75 mg**

**ACID
REDUCER**

**PREVENTS & RELIEVES
HEARTBURN** associated with acid
indigestion and sour stomach

60 TABLETS (60 DOSES)



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 75 mg Blister Carton (10 Tablets)

AUROHEALTH

NDC 58602-733-03

***Compare to the active ingredient in Zantac 75®**

Regular Strength

Ranitidine Tablets USP, 75 mg

ACID REDUCER

PREVENTS & RELIEVES
HEARTBURN associated with acid
indigestion and sour stomach

10 TABLETS (10 DOSES)

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



P1035338



NDC 58602-733-03

* Compare to the active
ingredient in Zantac 75®

Regular Strength

Ranitidine Tablets USP, 75 mg



**PREVENTS & RELIEVES
HEARTBURN** associated with acid
indigestion and sour stomach

10 TABLETS (10 DOSES)



- Tips for managing heartburn**
- If you are overweight, lose weight
 - If you smoke, quit smoking
 - Raise the head of your bed
 - Wear loose fitting clothing around your stomach

- 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



N 3 15 8 6 0 2 7 3 3 0 3 1 2

Made in India
Code: TS/DRUGS/22/2009
*This product is not manufactured or distributed by Chatterm, Inc
distributor of Zantac 75®

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

Drug Facts	
Active ingredient (in each tablet) Ranitidine 75 mg (as ranitidine hydrochloride USP 83.707 mg)....Acid reducer	Purpose
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) ■ do not chew tablet ■ children under 12 years: ask a doctor	
Other information ■ TAMPER EVIDENT: Do Not Use if The Carton Or Individual Blister Unit 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	

Lot:
EXP:

UNVARNISH ZONE
(Dotted lines not to be printed)



RANITIDINE
ranitidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-733
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	75 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (5 MPAS) (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	6 mm
Flavor		Imprint Code	K;42
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-733-09	1 in 1 CARTON	11/13/2017	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-733-15	1 in 1 CARTON	11/13/2017	
2		60 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-733-18	1 in 1 CARTON	11/13/2017	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-733-22	1 in 1 CARTON	11/13/2017	
4		105 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-733-23	1 in 1 CARTON	11/13/2017	
5		120 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-733-30	1 in 1 CARTON	11/13/2017	
6		160 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-733-40	1 in 1 CARTON	11/13/2017	
7		500 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-733-03	1 in 1 CARTON	11/13/2017	
8		10 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	ANDA207579	11/13/2017	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-733) , MANUFACTURE(58602-733)

Revised: 11/2019

Aurohealth LLC