

RANITIDINE- ranitidine tablet, film coated
Cardinal Health

Drug Facts

ACTIVE INGREDIENT (IN EACH TABLET)

Ranitidine 75 mg (as ranitidine hydrochloride USP, 84 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

- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- 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

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 (1-800-222-1222).

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° - 25° C (68° - 77° F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

INACTIVE INGREDIENTS

Colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, talc, titanium dioxide

QUESTIONS?

Call 1-800-406-7984

PRINCIPAL DISPLAY PANEL

NDC 49781-026-60

LEADER[®]

Compare to Zantac 75[®] active ingredient[†]

REGULAR STRENGTH

Acid Reducer

Ranitidine Tablets, USP 75 mg

Acid Reducer

Prevents & Relieves Heartburn Associated with Acid Indigestion & Sour Stomach

60 TABLETS

DISTRIBUTED BY CARDINAL HEALTH

5104347/0713



RANITIDINE

ranitidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49 78 1-026
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465HM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	75 mg

Inactive Ingredients

Ingredient Name	Strength
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	pink	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	OR;606
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-026-60	1 in 1 CARTON		
1		60 in 1 BOTTLE		
2	NDC:49781-026-30	1 in 1 CARTON		
2		30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201745	09/25/2013	

Labeler - Cardinal Health (097537435)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

Establishment			
Name	Address	ID/FEI	Business Operations
Shasun Pharmaceuticals Limited		915786829	manufacture(49781-026)