RANITIDINE- ranitidine tablet, coated
Wockhardt USA LLC.

Ranitidine Tablet USP, 75 mg

OTC - ACTIVE INGREDIENT SECTION

Ranitidine 75 mg (as ranitidine hydrochloride 84 mg)

OTC - PURPOSE SECTION

Acid reducer

USAGE

● 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

o frequent wheezing, particularly with heartburn

o frequent **chest pain**

o stomach pain

o unexplained weight loss

o nausea or vomiting

o had heartburn over 3 months. This may be a sign of a more serious condition.

o heartburn with **lightheadedness, sweating or dizziness**.

o 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

o your heartburn continues or worsens

o you need to take this product for more than 14 days

PREGNANCY OR BREAST FEEDING

If pregnant or breast-feeding, ask a health professional before use.

OTC - KEEP OUT OF REACH OF CHILDREN

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

- Blister: Do not use if individual unit is open or torn
- Bottle: do not use if printed foil under bottle cap is open or torn
- store at 20°-25°C (68°-77°F)
- avoid excessive heat or humidity
- this product is sugar free

INACTIVE INGREDIENT

colloidal silicon dioxide, croscarmellose sodium, diethyl phthalate, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose and titanium dioxide.

QUESTIONS OR COMMENTS

Call **1-800-346-6854**

Read the directions, consumer information leaflet and warnings before use. Keep the carton. It contains important information.

Manufactured by:

Wockhardt Limited,

Mumbai, India.

Distributed by:

Wockhardt USA LLC.

20 Waterview Blvd.

Parsippany, NJ 07054

USA.

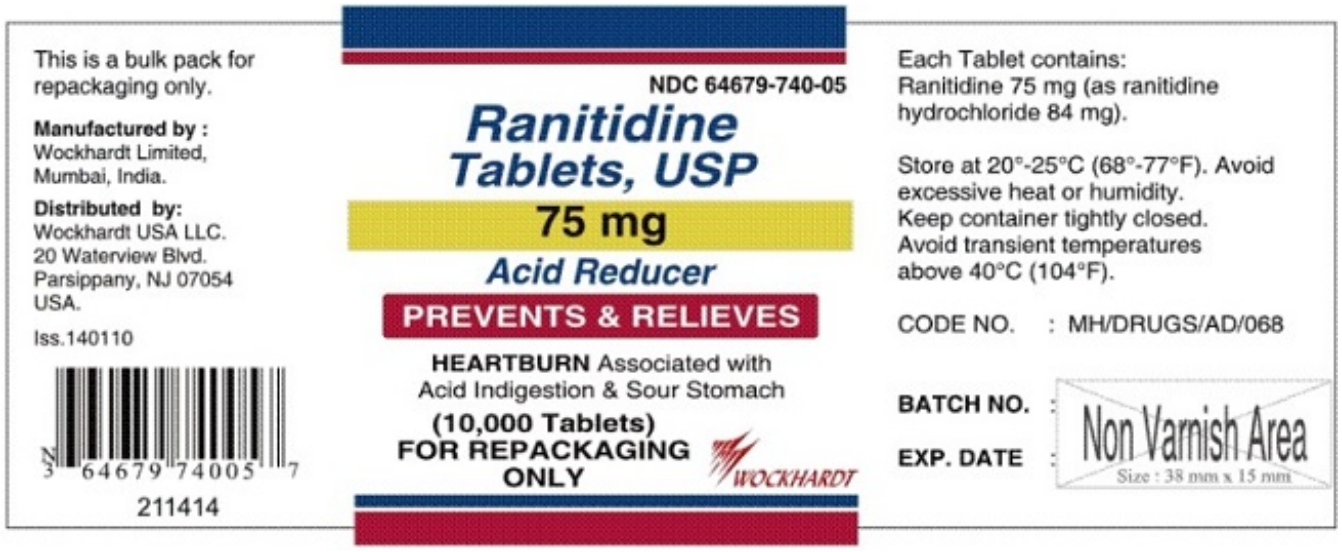
Iss.020410

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ranitidine Tablets USP, 75 mg (OTC)

75 mg - Acid reducer

64679-740-05



RANITIDINE

ranitidine tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64679-740
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIETHYL PHTHALATE (UNII: UF064M00AF)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	PINK (Pink colored film coated)	**Score**	no score
Shape	HEXAGON (6 SIDED)	**Size**	8mm
Flavor		**Imprint Code**	W;75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64679-740-01	1 in 1 CARTON	07/31/2008	
1		10 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:64679-740-02	1 in 1 CARTON	07/31/2008	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:64679-740-04	1 in 1 CARTON	07/31/2008	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:64679-740-03	10 in 1 CARTON	07/31/2008	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:64679-740-05	10000 in 1 POUCH; Type 0: Not a Combination Product	07/31/2008	
6	NDC:64679-740-00	60000 in 1 DRUM; Type 0: Not a Combination Product	07/31/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078884	07/31/2008	

Labeler - Wockhardt USA LLC. (170508365)

Registrant - Wockhardt Limited (650069115)

Establishment

Name	Address	ID/FEI	Business Operations
Wockhardt Limited		676257570	ANALYSIS(64679-740) , LABEL(64679-740) , MANUFACTURE(64679-740) , PACK(64679-740)

Revised: 12/2018 Wockhardt USA LLC.