

RANITIDINE - ranitidine tablet, coated
WOCKHARDT LIMITED

Active ingredient (in each tablet)

Ranitidine 75 mg (as ranitidine hydrochloride 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 wheezing, particularly with heartburn
- frequent **chest pain**
- stomach pain
- unexplained weight loss
- nausea or vomiting
- 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.

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 ingredients

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

Bottle sealed with printed foil under cap. Do not use if foil is open or torn.

NDC 64679-740-04

Ranitidine

Tablets, USP

75 mg

Acid Reducer

PREVENTS & RELIEVES

HEARTBURN Associated with
Acid Indigestion & Sour Stomach

500 Tablets
(500 Doses)

MH/DRUGS/AD/068

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

Active ingredient (In each tablet) Ranitidine 75 mg (as ranitidine hydrochloride 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 wheezing, particularly with heartburn • frequent chest pain • stomach pain • unexplained weight loss • nausea or vomiting • 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. **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 • store at 20°-25°C (68°-77°F) • avoid excessive heat or humidity • this product is sugar free

This package is for households without young children.

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3 64679 174004 0

Lot:
Exp.:

Iss.090609

Non Varnish Area

Drug Facts

Active ingredient (in each tablet) Ranitidine 75 mg (as ranitidine hydrochloride 84 mg)	Purpose Acid reducer
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Uses

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- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings

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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.
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Drug Facts (continued)

Ask a doctor before use if you have

- frequent wheezing, particularly with heartburn
- unexplained weight loss
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness.**
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Drug Facts (continued)

Inactive ingredients 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.

MH/DRUGS/AD/068



Lot:
Exp.:


Bottle contains desiccant.

NDC 64679-740-04

**Ranitidine
Tablets, USP
75 mg
Acid Reducer**

PREVENTS & RELIEVES
HEARTBURN Associated with
Acid Indigestion & Sour Stomach

500 Tablets
(500 Doses)

 **WOCKHARDT**

Manufactured by:
Wockhardt USA LLC,
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Distributed by:
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USA.

Iss: 090609

RANITIDINE

ranitidine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55648-740
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIETHYL PHTHALATE (UNII: UF064M00AF)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

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:55648-740-01	1 in 1 CARTON		
1		10 in 1 BOTTLE		
2	NDC:55648-740-02	1 in 1 CARTON		
2		100 in 1 BOTTLE		
3	NDC:55648-740-04	1 in 1 CARTON		
3		500 in 1 BOTTLE		
4	NDC:55648-740-03	10 in 1 CARTON		
4		10 in 1 BLISTER PACK		
5	NDC:55648-740-05	10000 in 1 POUCH		
6	NDC:55648-740-00	60000 in 1 DRUM		

Marketing Information

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

Labeler - WOCKHARDT LIMITED (650069115)

Establishment

Name	Address	ID/FEI	Business Operations
WOCKHARDT LIMITED		676257570	manufacture

Revised: 11/2011

WOCKHARDT LIMITED