

RANITIDINE - ranitidine tablet, coated
WOCKHARDT LIMITED

Drug Facts

Active ingredient (in each tablet)

Ranitidine 150 mg (as ranitidine hydrochloride 168 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 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
- if you have kidney disease, except under the advice and supervision of a doctor

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.

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, FD and C yellow # 6 aluminum lake, 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.

Rev.151111

Contains FD&C Yellow No. 6 as a color additive.

Store at 20°-25°C (68°-77°F).
Avoid excessive heat or humidity.
Bottle contains desiccant.

Manufactured by:
Wockhardt Limited,
Mumbai, India.

Distributed by:
Wockhardt USA LLC,
20 Waterview Blvd.
Parsippany, NJ 07054
USA.

Iss.090609

NDC 64679-741-05

MAXIMUM STRENGTH
Ranitidine
Tablets, USP

150 mg

Acid Reducer

PREVENTS & RELIEVES

HEARTBURN Associated with
Acid Indigestion & Sour Stomach

500 Tablets
(500 Doses)



IMPORTANT: SEE CARTON OR LEAFLET FOR COMPLETE INFORMATION.

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



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

LOT:
EXP.:

MH/DRUGS/AD/068

Drug Facts

Active ingredient (in each tablet)

Ranitidine 150 mg (as ranitidine hydrochloride 168 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 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.

Drug Facts (continued)

Do not use (continued)

- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor

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.

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

Drug Facts (continued)

Other information

- do not use if 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

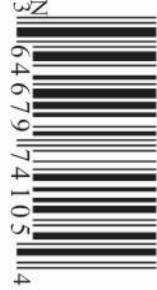
Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, diethyl phthalate, FD&C yellow # 6 aluminum lake, 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.



MHIDRUGSAD068

Lot:

Exp.:

Bottle contains desiccant.

Manufactured by:
Wockhardt Limited,
Mumbai, India.

Distributed by:
Wockhardt USA LLC,
20 Waterview Blvd.
Parsippany, NJ 07054
USA.

Rev.151111

NDC 64679-741-05

MAXIMUM STRENGTH
Ranitidine
Tablets, USP

150 mg

Acid Reducer

PREVENTS & RELIEVES

HEARTBURN Associated with
Acid Indigestion & Sour Stomach

500 Tablets
(500 Doses)



RANITIDINE

ranitidine tablet, coated

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55648-741 |
| 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 |
|--|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| DIETHYL PHTHALATE (UNII: UF064M00AF) | |

Product Characteristics

| | | | |
|----------|-------------------------------------|--------------|----------|
| Color | orange (orange colored film coated) | Score | no score |
| Shape | HEXAGON (6 sided) | Size | 10mm |
| Flavor | | Imprint Code | W741 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------|----------------------|--------------------|
| 1 | NDC:55648-741-01 | 1 in 1 CARTON | | |
| 1 | | 10 in 1 BOTTLE | | |
| 2 | NDC:55648-741-02 | 1 in 1 CARTON | | |
| 2 | | 100 in 1 BOTTLE | | |
| 3 | NDC:55648-741-05 | 1 in 1 CARTON | | |
| 3 | | 500 in 1 BOTTLE | | |
| 4 | NDC:55648-741-03 | 10 in 1 CARTON | | |
| 4 | | 10 in 1 BLISTER PACK | | |
| 5 | NDC:55648-741-06 | 6000 in 1 POUCH | | |
| 6 | NDC:55648-741-00 | 30000 in 1 DRUM | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA078653 | 11/26/2007 | |

Labeler - WOCKHARDT LIMITED (650069115)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|---------------------|
| WOCKHARDT LIMITED | | 676257570 | manufacture |

Revised: 11/2011

WOCKHARDT LIMITED