

**RANITIDINE- ranitidine tablet**  
**Medline Industries, Inc.**

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**Drug Facts**

**ACTIVE INGREDIENT (IN EACH TABLET)**

Ranitidine 150 mg (as ranitidine hydrochloride USP, 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 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
- 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 (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 INDIVIDUAL BLISTER UNIT 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, talc, titanium dioxide

## **QUESTIONS?**

Call **1-800-MEDLINE (633-5463), Monday - Friday, 9AM - 5PM CST**

## **PRINCIPAL DISPLAY PANEL**

**MEDLINE**

**NDC 53329-695-68**

**†Compare to the active ingredient of Zantac 150<sup>®</sup>**

**Maximum Strength**

**RANITIDINE TABLETS, USP 150 mg**

**ACID REDUCER**

**Prevents & Relieves**

**Heartburn Associated with Acid Indigestion & Sour Stomach**

**150 mg**

**24 TABLETS**

**Distributed by: Medline Industries, Inc.**

**5099014/1012**





# RANITIDINE

ranitidine tablet

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:53329-695 |
| Route of Administration | ORAL           |                    |               |

| Active Ingredient/Active Moiety                                             |  |                   |          |
|-----------------------------------------------------------------------------|--|-------------------|----------|
| Ingredient Name                                                             |  | Basis of Strength | Strength |
| RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10 YB7) |  | RANITIDINE        | 150 mg   |

| Inactive Ingredients                           |          |
|------------------------------------------------|----------|
| Ingredient Name                                | Strength |
| COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)   |          |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)       |          |
| HYPROMELLOSES (UNII: 3NXW29V3WO)               |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)            |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)          |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) |          |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)        |          |
| TALC (UNII: 7SEV7J4R1U)                        |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)            |          |

| Product Characteristics |                                  |              |          |
|-------------------------|----------------------------------|--------------|----------|
| Color                   | white (Off-White to Pale Yellow) | Score        | no score |
| Shape                   | OVAL                             | Size         | 7mm      |
| Flavor                  |                                  | Imprint Code | 9R       |
| Contains                |                                  |              |          |

| Packaging |                  |                      |                      |                    |
|-----------|------------------|----------------------|----------------------|--------------------|
| #         | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
| 1         | NDC:53329-695-68 | 24 in 1 BLISTER PACK |                      |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| ANDA               | ANDA200536                               | 03/30/2012           |                    |

**Labeler** - Medline Industries, Inc. (025460908)

**Registrant** - Ranbaxy Pharmaceuticals Inc. (937890044)

## Establishment

| Name                           | Address | ID/FEI    | Business Operations    |
|--------------------------------|---------|-----------|------------------------|
| Shasun Pharmaceuticals Limited |         | 915786829 | manufacture(53329-695) |

Revised: 3/2013

Medline Industries, Inc.