**RANITIDINE- ranitidine tablet, film coated**
**Sunmark**

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**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**

**sunmark®**

***COMPARE TO ZANTAC 75® ACTIVE INGREDIENT**

**NDC 49348-473-12**

**Ranitidine Tablets, USP 75 mg**

**acid reducer**

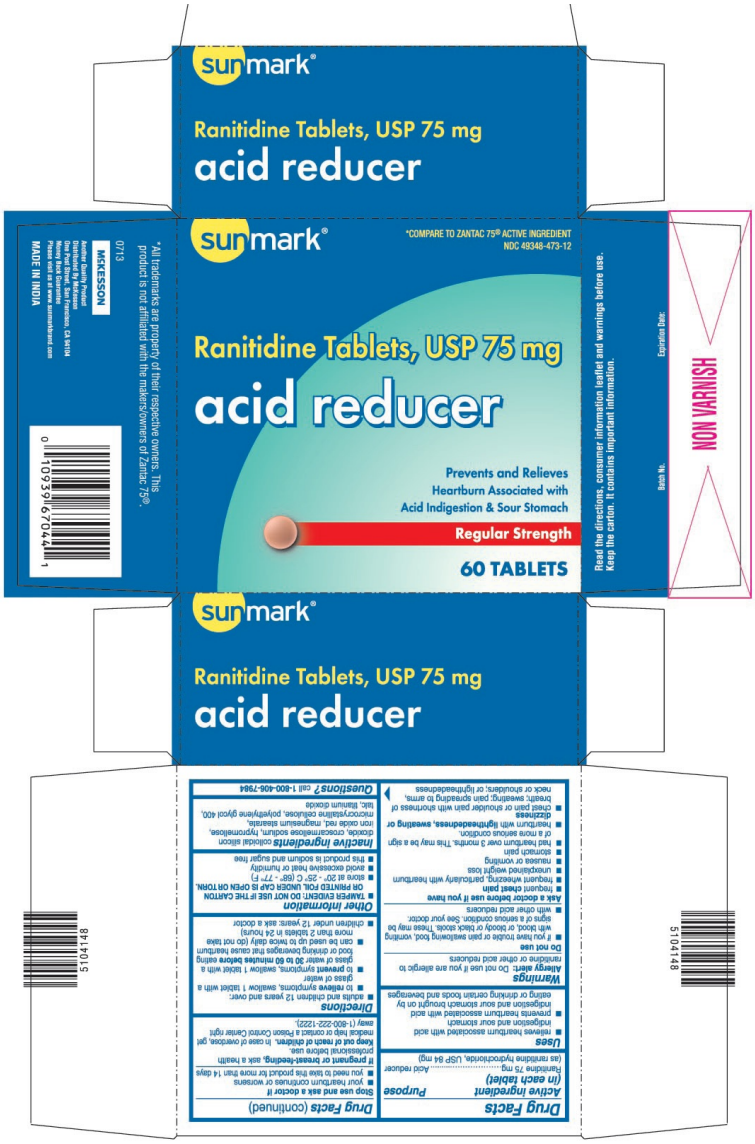
**Prevents and Relieves Heartburn Associated with Acid Indigestion & Sour Stomach**

**Regular Strength**

**60 TABLETS**

**Distributed By McKesson**

**5104148/0713**




# RANITIDINE

ranitidine tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:49348-473 |
| **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** |
| **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 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:49348-473-12 | 1 in 1 CARTON | | |
| **1** | | 60 in 1 BOTTLE | | |
| **2** | NDC:49348-473-44 | 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 | 09/20/2013 | |

## Labeler - Sunmark (177667227)

## Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Shasun Pharmaceuticals Limited | | 915786829 | manufacture(49348-473) |

Revised: 8/2013 Sunmark