RANITIDINE- ranitidine hydrochloride tablet, film coated Chain Drug Marketing Association Inc.

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

QC QUALITY CHOICE®

NDC 63868-711-30

*Compare to the active ingredient in Zantac 75®

REGULAR STRENGTH

HEARTBURN

75 RANITIDINE TABLETS, USP 75 mg

ACID REDUCER

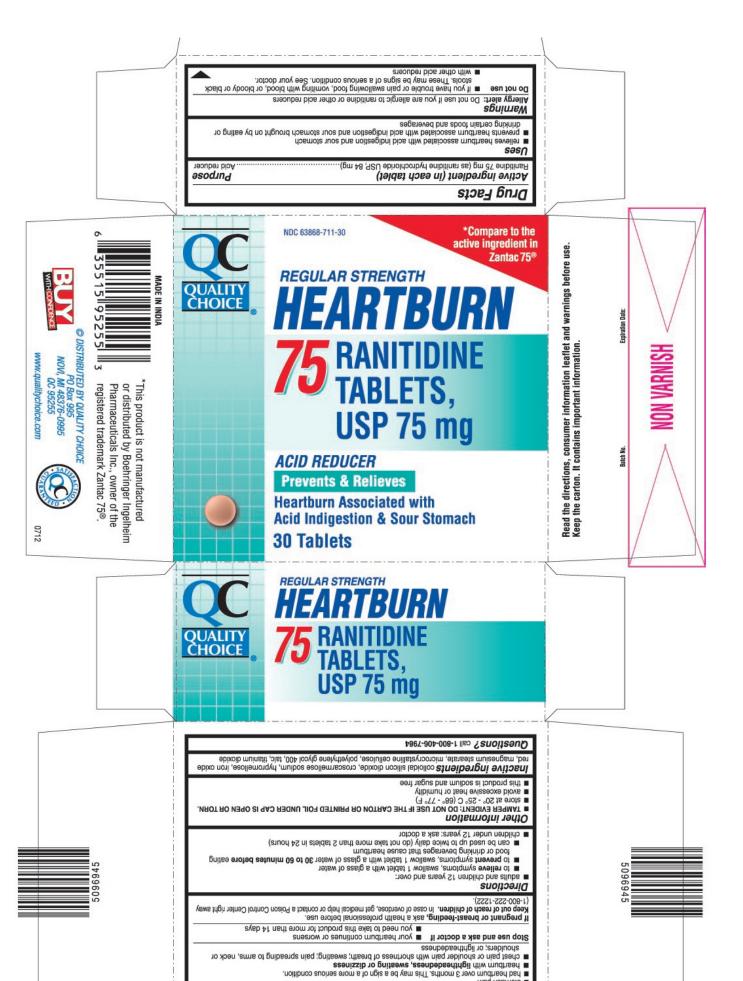
Prevents & Relieves

Heartburn Associated with Acid Indigestion & Sour Stomach

30 Tablets

© DISTRIBUTED BY QUALITY CHOICE

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■ nausea or vomiting

ILIGHT CUGSI DSIU

■ frequent wheezing, particularly with heartburn unexplained weight loss

RANITIDINE

ranitidine hydrochloride tablet, film coated

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-711 |
|--------------|----------------|--------------------|---------------|
|--------------|----------------|--------------------|---------------|

Route of Administration ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
| | | |

RANITIDINE HYDRO CHLO RIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10 YB7) RANITIDINE 75 mg

Inactive Ingredients

| macuve ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| COLLOIDAL SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) | | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | | |
| TALC (UNII: 7SEV7J4R1U) | | |

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

Product Characteristics

| Color | pink | Score | no score |
|----------|-------|--------------|----------|
| Shape | ROUND | Size | 8 mm |
| Flavor | | Imprint Code | OR;606 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:63868-711-30 | 30 in 1 BOTTLE | | |
| 2 | NDC:63868-711-60 | 60 in 1 BOTTLE | | |

Marketing Information

Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date

| ANDA | ANDA201745 | 07/10/2012 | |
|------|------------|------------|--|
| | | | |

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Ohm Laboratories Inc. (184769029)

| Establishment | | | | |
|--------------------------------|---------|-----------|-------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Shasun Pharmaceuticals Limited | | 915786829 | manufacture (63868-711) | |

Revised: 9/2012 Chain Drug Marketing Association Inc.