# ACID REDUCER- ranitidine tablet, film coated NuCare Pharmaceuticals, Inc.

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**GC765D** 

## 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

- 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
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

## 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 healthcare 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**

- do not chew tablet
- swallow tablet with a glass of water
- adults and children 12 years and over:
  - to relieve symptoms, take 1 tablet
  - to prevent symptoms, take 1 tablet 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°C to 25°C (68°F to 77°F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

## Inactive ingredients

FD&C red #40 aluminum lake, hypromellose, iron oxide black, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

#### **Questions?**

Call **1-800-540-3765** 

## **Principal Display Panel**



## **ACID REDUCER**

ranitidine tablet, film coated

| Product Information     |                |                    |                               |  |
|-------------------------|----------------|--------------------|-------------------------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68071-5012(NDC:57896-715) |  |
| Route of Administration | ORAL           |                    |                               |  |

| Active Ingredient/Active Moiety  |                      |          |  |
|--|----------------------|----------|--|
| Ingredient Name  | Basis of<br>Strength | Strength |  |
| RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7) | RANITIDINE           | 75 mg    |  |

| Inactive Ingredients                                |          |  |  |
|---|----------|--|--|
| Ingredient Name                                     | Strength |  |  |
| HYPROMELLOSES (UNII: 3NXW29V3WO)                    |          |  |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)               |          |  |  |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)      |          |  |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |  |  |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                 |          |  |  |
| FERROSOFERRIC OXIDE (UNII: XM0M87F357)              |          |  |  |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                  |          |  |  |

| Product Characteristics |       |              |          |  |
|-------------------------|-------|--------------|----------|--|
| Color                   | pink  | Score        | no score |  |
| Shape                   | ROUND | Size         | 7mm      |  |
| Flavor                  |       | Imprint Code | P75      |  |
| Contains                |       |              |          |  |

| Packaging            |   |                         |                       |
|----------------------|---|-------------------------|-----------------------|
| # Item Code          | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |
| NDC:68071-<br>5012-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 08/01/2019              |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA                  | ANDA075294                                  | 10/01/2018              |                       |
|                       |   |                         |                       |

| Establishment                |         |           |                            |  |
|------------------------------|---------|-----------|----------------------------|--|
| Name                         | Address | ID/FEI    | <b>Business Operations</b> |  |
| NuCare Pharmaceuticals, Inc. |         | 010632300 | relabel(68071-5012)        |  |

Revised: 2/2021 NuCare Pharmaceuticals,Inc.