# RANITIDINE- ranitidine tablet, coated Chain Drug Marketing Association

-----

# **Drug Facts**

# Active ingredient (in each tablet)

Ranitidine 150 mg (as ranitidine hydrochloride USP, 168 mg)

# **Purpose**

Acid reducer

# Use(s)

- 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

- 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 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

- 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
- protect from light
- 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 1-888-375-3784

#### Carton Label



#### **Bottle label**



### **RANITIDINE**

ranitidine tablet, coated

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:63868-480(NDC:55111-404) Route of Administration ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength Ranitidine Hydrochloride (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7) RANITIDINE 150 mg

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)			
FERROSOFERRIC OXIDE (UNII: XM0M87F357)			
magnesium stearate (UNII: 70097M6I30)			
cellulose, microcrystalline (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
titanium dioxide (UNII: 15FIX9V2JP)			

Product Characteristics					
Color	PINK	Score	no score		
Shape	ROUND	Size	9mm		
Flavor		Imprint Code	R150		
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63868-480- 50	1 in 1 CARTON	07/01/2018	09/30/2019		
1		50 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:63868-480- 24	1 in 1 CARTON	07/01/2018	09/30/2019		
2		24 in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA078192	07/01/2018			

# **Registrant -** Dr. Reddy's Laboratories Limited (650562841)

Revised: 9/2019

Chain Drug Marketing Association