RANITIDINE- ranitidine tablet
Chain Drug Marketing Association

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

- 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 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)
  - do not chew tablet
- children under 12 years: ask a doctor

Other information

- do not use if carton or printed foil under cap is open or torn
- avoid excessive heat or humidity
- store at 20°-25°C (68°-77°F)
- this product is sodium and sugar free

Inactive ingredients

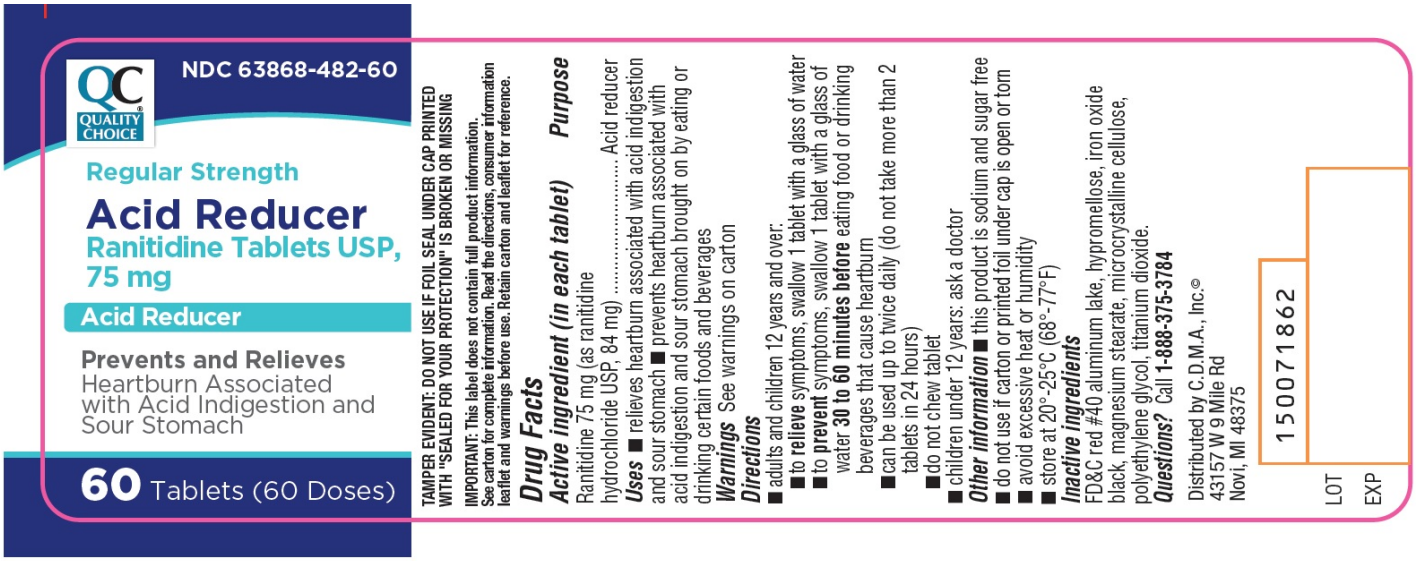
FD&C red #40 aluminum lake, hypromellose, iron oxide black, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

Questions?

Call **1-888-375-3784**

Read the directions, consumer information leaflet and warnings before use. Keep the carton. It contains important information.

Bottle label



Carton label

RANITIDINE

ranitidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-482(NDC:55111-131)

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
Hypromelloses (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
cellulose, microcrystalline (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WQ0SDW1A)	
ferrosoferric oxide (UNII: XM0M87F357)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	P75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-482-30	1 in 1 CARTON	07/01/2018	09/30/2019
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63868-482-60	1 in 1 CARTON	07/01/2018	09/30/2019
2		60 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	ANDA075294	07/01/2018	

Labeler - Chain Drug Marketing Association (011920774)

Revised: 9/2019 Chain Drug Marketing Association