RANITIDINE- ranitidine tablet, coated
Dr. Reddy's Laboratories Limited

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

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
- kidney disease

Ask a doctor or pharmacist before use if you are

• taking a prescription drug. Acid reducers may interact with certain prescription drugs.

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 (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

- 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**

Read the directions and warnings before use. Keep the carton. It contains important information including tips for managing heartburn.

Tips for managing heartburn

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, and even some fruits and vegetables.
- Eat slowly and do not eat beig meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach.

Revised: 03/20

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

Container Label:

Dr.Reddy's
NDC 55111-404-34

Maximum Strength

Ranitidine
Tablets USP,150 mg
ACID REDUCER

PREVENTS & RELIEVES
HEARTBURN associated with acid indigestion
and sour stomach

24 *Tablets(24 doses)*

Container Carton Label:

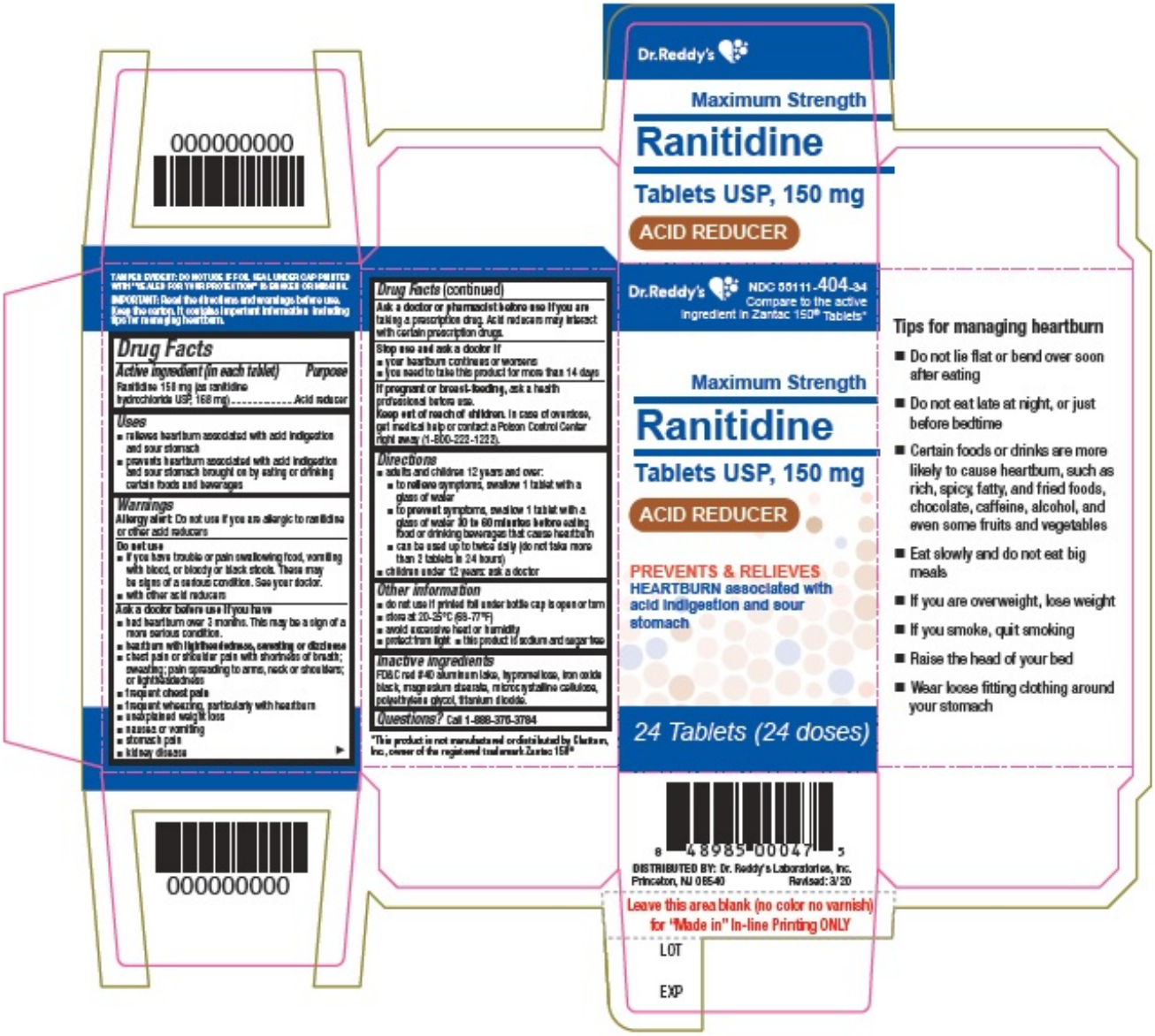
Dr.Reddy's
NDC 55111-404-34

Compare to the active
ingredient in Zantact 150® Tablets*

Maximum Strength
Ranitidine
Tablets USP,150 mg
ACID REDUCER

PREVENTS & RELIEVES
heartburn associated with acid indigestion
and sour stomach

24 *Tablets(24 doses)*



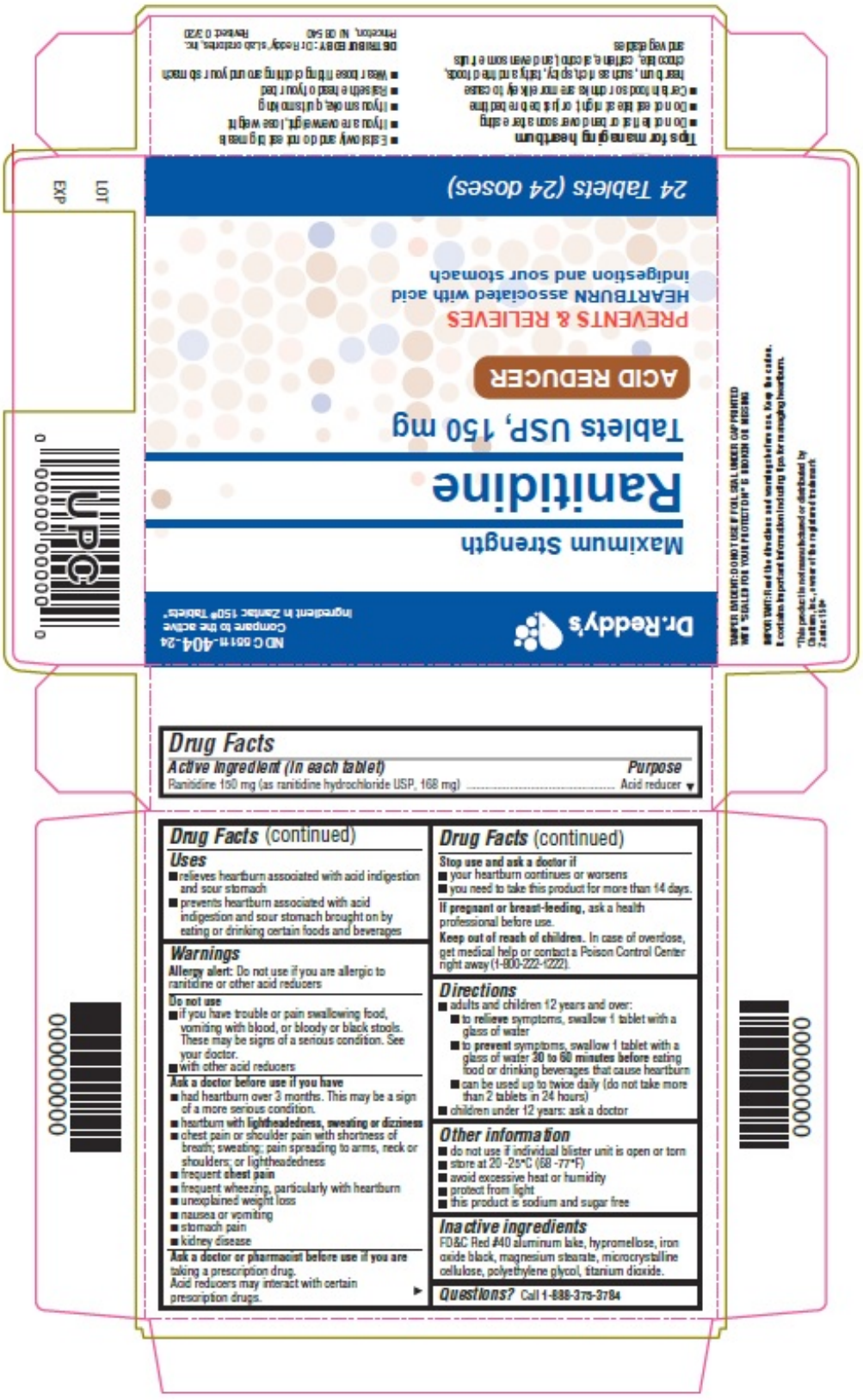
Blister Carton Label:

Dr.Reddy's
NDC 55111-404-24

Maximum Strength
Ranitidine
Tablets USP,150 mg
ACID REDUCER

PREVENTS & RELIEVES
HEARTBURN associated with acid indigestion
and sour stomach

24 *Tablets(24 doses)*



RANITIDINE

ranitidine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55111-404
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55111-404-34	1 in 1 CARTON	12/02/2009	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55111-404-32	1 in 1 CARTON	12/02/2009	
2		32 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:55111-404-36	1 in 1 CARTON	12/02/2009	
3		36 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:55111-404-50	1 in 1 CARTON	12/02/2009	
4		50 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:55111-404-61	1 in 1 CARTON	12/02/2009	
5		65 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:55111-404-55	2 in 1 CARTON	01/05/2010	
6		65 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:55111-404-62	1 in 1 CARTON	12/02/2009	
7		95 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:55111-404-90	2 in 1 CARTON	12/02/2009	
8		95 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:55111-404-02	1 in 1 CARTON	12/02/2009	
9		200 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:55111-404-65	1 in 1 CARTON	12/02/2009	
10		220 in 1 BOTTLE; Type 0: Not a Combination Product		

11	NDC:55111-404-17	1 in 1 CARTON	12/02/2009	
11		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
12	NDC:55111-404-24	3 in 1 CARTON	12/02/2009	
12		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
13	NDC:55111-404-38	4 in 1 CARTON	12/02/2009	
13		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
14	NDC:55111-404-40	1 in 1 BOTTLE	12/02/2009	
14		40 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	12/02/2009	

Labeler - Dr. Reddy's Laboratories Limited (650562841)

Revised: 4/2020 Dr. Reddy's Laboratories Limited