RANITIDINE- ranitidine tablet
AvPAK

Ranitidine Tablets, USP

ACTIVE INGREDIENT(S)

Ranitidine 150 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

- 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

PREGNANCY/BREASTFEEDING

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 (for cool mint tablets only)
 children under 12 years: ask a doctor

OTHER INFORMATION

· safety sealed: do not use if carton is opened or if printed foil inner seal on bottle is torn or missing

· store between 20°and 25°C (68°and 77°F)

· protect from excessive moisture and light

INACTIVE INGREDIENTS

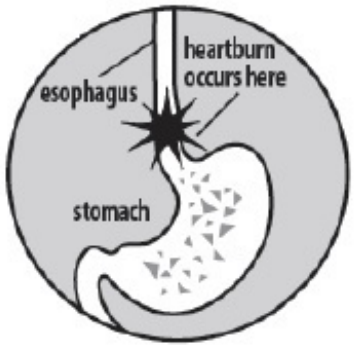
For 150 mg:croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol,talcum, titanium dioxide

For 150 mg cool mint:acacia, croscarmellose sodium, FD&C Blue No. 1,magnesium stearate, menthol, microcrystalline cellulose,polyethylene glycol, polyvinyl alcohol, talcum,
titanium dioxide

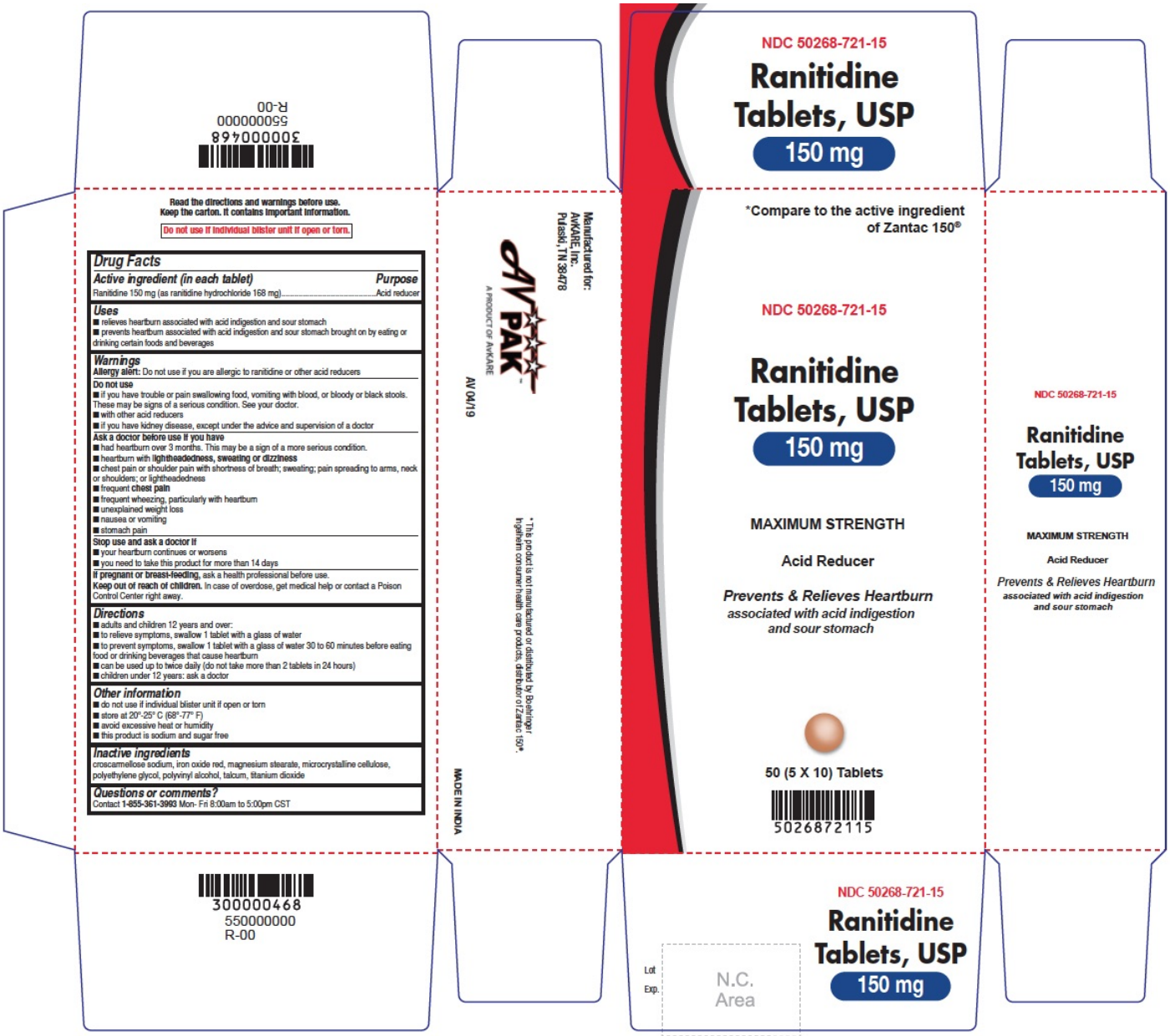
Questions or comments?

Contact 1-855-361-3993

CONSUMER INFORMATION



PRINCIPAL DISPLAY PANEL



RANITIDINE

ranitidine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50268-721
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**

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	150;G
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-721-15	50 in 1 BOX	05/17/2019	
1	NDC:50268-721-11	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210243	05/17/2019	

Labeler - AvPAK (832926666)

Revised: 5/2019 AvPAK