# ACID REDUCER- ranitidine hydrochloride tablet, film coated

WinCo Foods, LLC

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## **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

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

## 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 (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**

- TAMPER EVIDENT: DO NOT USE IF THE CARTON OR INDIVIDUAL BLISTER UNIT IS OPEN OR TORN.
- store at 20° 25° C (68° 77° F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

#### **INACTIVE INGREDIENTS**

Colloidal silicon dioxide, croscarmellose sodium, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, talc, titanium dioxide

## **QUESTIONS?**

or to report an adverse event call 800-824-1706 Monday - Friday 9am - 4pm MST

## PRINCIPAL DISPLAY PANEL

Compare to the active ingredient in Zantac75<sup>®</sup>

#### WinCo FOODS

REGULAR STRENGTH

## Acid Reducer

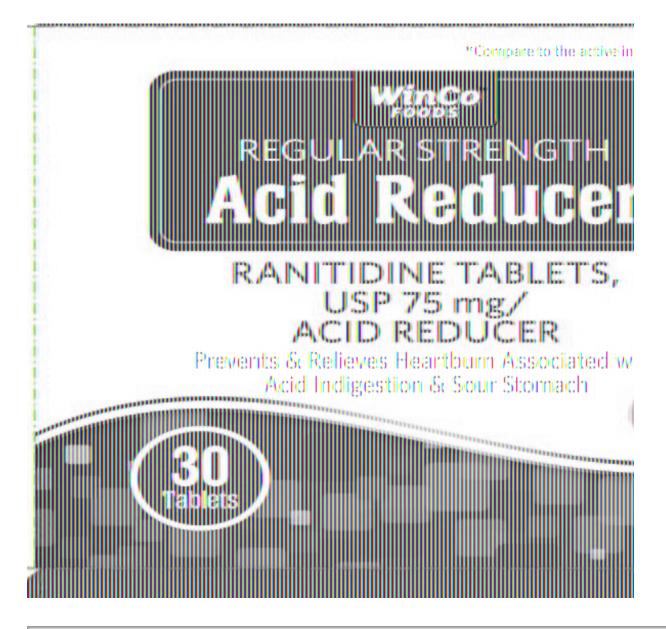
## **RANITIDINE TABLETS, USP 75 mg/ ACID REDUCER**

Prevents & Relieves Heartburn Associated with Acid Indigestion & Sour Stomach

#### 30 Tablets

## DISTRIBUTED BY: WinCo FOODS, LLC, BOISE, ID 83704

## 5113307/0914



## ACID REDUCER

ranitidine hydrochloride tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-244	
Route of Administration	ORAL			

Active Ingredient/Active Molety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
RANITIDINE HYDRO CHLO RIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	75 mg	

Inactive Ingredients

Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			

HYPROMELLOSES (U					
FERRIC OXIDE RED (U	,				
	,				
MAGNESIUM STEARA					
	CRYSTALLINE (UNII: OP1	,			
	<b>COL 400</b> (UNII: B697894	48GQ)			
TALC (UNII: 7SEV7J4R	,				
TITANIUM DIO XIDE (	UNII: 15FIX9V2JP)				
Developed Character					
Product Characte					
Color	pink	Score		10 score 3mm	
Shape	ROUND	Size	Size		
Flavor		Imprint Code	(	OR;606	
Contains					
Packaging					
# Item Code	Package Description		Marketing Start Date	Marketing End Date	
1 NDC:67091-244-30	1 in 1 CARTON	1 CARTON			
1	30 in 1 BOTTLE; Type 0: Not a Combination Product				
	.•				
Marketing Information					
Marketing Category	Application Numbe	r or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA201745		08/02/2012		

Labeler - WinCo Foods, LLC (056098817)

Registrant - Ranbaxy Pharmaceuticals Inc. (937890044)

## Establishment

Name	Address	ID/FEI	Business Operations
Shasun Pharmaceuticals Limited		915786829	MANUFACTURE(67091-244)

Revised: 12/2014

WinCo Foods, LLC