ZANTAC- ranitidine tablet, coated
Central Texas Community Health Centers

Zantac 75® Drug Facts

Drug Facts

Active ingredient (in each tablet)	*Purpose*
Ranitidine 75 mg (as ranitidine hydrochloride 84 mg)	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 printed foil under bottle cap is open or torn (bottles)
- do not use if individual blister unit is open or torn (blisters)
- do not use if individual foil packet is open or torn (pouch)
- store at 20-25ºC (68-77ºF)
- avoid excessive heat or humidity
- this product is sodium and sugar free

Inactive ingredients

hypromellose, magnesium stearate, microcrystalline cellulose, iron oxide, titanium dioxide, triacetin

Questions?

call **1-888-285-9159** (English/Spanish) M – F, 8:30 – 5 EST, or visit **www.zantacotc.com**

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

Distributed by: Boehringer Ingelheim (BI) Consumer Health Care Products
Division of BI Pharmaceuticals, Inc., Ridgefield, CT 06877

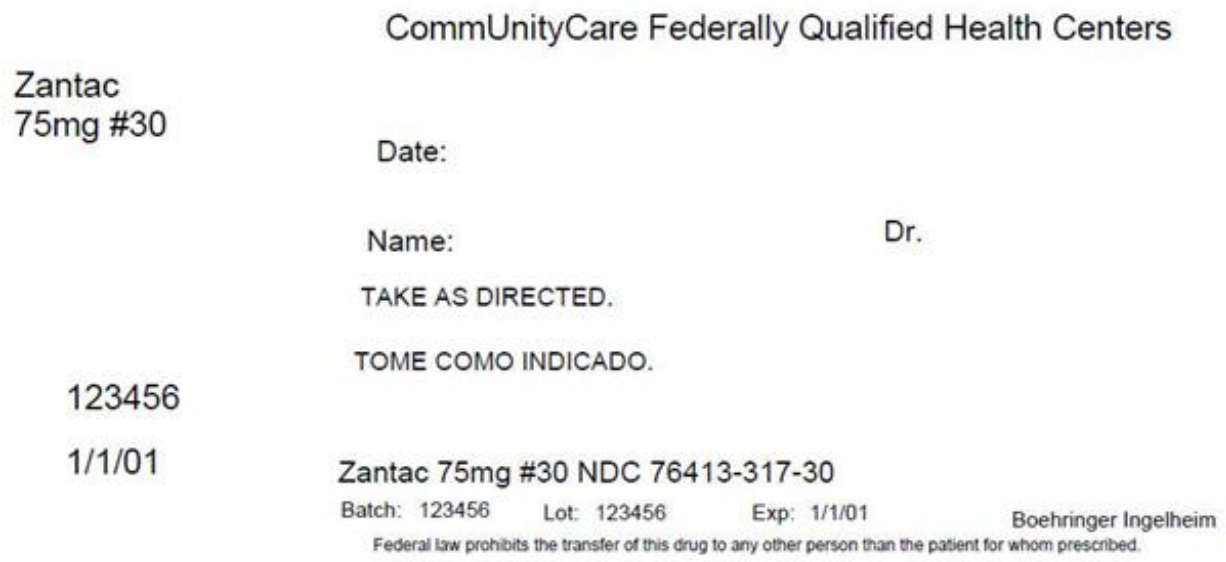
Product of Spain. Manufactured in Mexico.

HOW SUPPLIED

Product: 76413-317

NDC: 76413-317-30 10 TABLET, COATED in a BLISTER PACK / 3 in a CARTON

Zantac



ZANTAC

ranitidine tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76413-317(NDC:0597-0122)
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**
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ferric oxide red (UNII: 1K09F3G675)	
titanium dioxide (UNII: 15FIX9V2JP)	
triacetin (UNII: XHX3C3X673)	

Product Characteristics			
Color	PINK	**Score**	no score
Shape	PENTAGON (5 sided)	**Size**	3mm
Flavor		**Imprint Code**	Z;75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-317-30	3 in 1 CARTON	12/21/2006	
1		10 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
NDA	NDA020520	12/21/2006	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Travis County Healthcare District		797039398	RELABEL(76413-317) , REPACK(76413-317)

Revised: 4/2018 Central Texas Community Health Centers