# ACID REDUCER- ranitidine tablet Select Brand

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**Drug Facts** 

# **ACTIVE INGREDIENT (IN EACH TABLET)**

Ranitidine 150 mg (as ranitidine hydrochloride USP, 168 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 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 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, talc, titanium dioxide

# **QUESTIONS?**

Call 1-800-406-7984

#### PRINCIPAL DISPLAY PANEL

select brand®

NDC 15127-340-24

**Maximum Strength** 

Ranitidine Tablets, USP 150 mg

**Acid Reducer** 

Prevents & Relieves Heartburn Associated wit Acid Indigestion & Sour Stomach

<sup>†</sup>Compare to the active ingredient of Zantac 150<sup>®</sup>

24 Tablets

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Keep the carton. It contains important information Read the directions, consumer information leaflet and warnings before use. Questions? call 1-800-406-7984 ■ You need to take this product for more than your heartburn continues or worsens microcrystalline cellulose, polyethylene glycol, talc, Stop use and ask a doctor if hypromellose, iron oxide red, magnesium stearate, colloidal silicon dioxide, croscarmellose sodium, or shoulders; or lightheadedness Inactive ingredients preath; sweating; pain spreading to arms, neck chest pain or shoulder pain with shortness of ■ this product is sodium and sugar free SSƏUIZZID avoid excessive heat or humidity ■ heartburn with lightheadedness, sweating or ■ store at 20° - 25° C (68° - 77° F) sign of a more serious condition ореи ов тови. ■ had heartburn over 3 months. This may be a CARTON OR INDIVIDUAL BLISTER UNIT IS stomach pain ■ TAMPER EVIDENT: DO NOT USE IF THE ■ nausea or vomiting Other information ■ unexplained weight loss ■ frequent wheezing, particularly with heartburn ■ children under 12 years: ask a doctor uedneur cuest baiu ■ can be used up to twice daily (do not take more than 2 tablets in 24 hours) Ask a doctor before use if you have реальит eating food or drinking beverages that cause and supervision of a doctor a glass of water 30 to 60 minutes before It you have kidney disease, except under the advice ■ with other acid reducers to prevent symptoms, swallow 1 tablet with glass of water your doctor ■ to relieve symptoms, swallow 1 tablet with a These may be signs of a serious condition. See squits and children 12 years and over: vomiting with blood, or bloody or black stools. Directions if you have trouble or pain swallowing food, Do not use right away (1-800-222-1222). get medical help or contact a Poison Control Center ranitidine or other acid reducers Keep out of reach of children. In case of overdose, Allergy alert: Do not use if you are allergic to professional before use. Warnings If pregnant or breast-feeding, ask a health Drug Facts (continued) Drug Facts (continued) oods and beverages ■ prevents heartburn associated with acid indigestion and sour stomach brought on by certain Active ingredient (in each tablet)
Ranitidine 150 mg (as ranitidine hydrochloride USP, 168 mg) Purpose Drug Facts NDC 15127-340-24 the lower price name brand **Maximum Strength** Ranitidine Tablets, USP 150 mg **Acid Reducer Prevents & Relieves Heartburn Associated with Acid Indigestion & Sour Stomach** <sup>†</sup>Compare to the active ingredient of Zantac 150®

This product is not manufactured or distributed by

Boehringer Ingelheim Pharmaceuticals Inc., owner of the registered trademark Zantac 150<sup>®</sup>.



Distributed by: SELECT BRAND® DISTRIBUTORS Pine Bluff, AR 71603 USA AC 870-535-3635 MADE IN INDIA



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**ACID REDUCER** 

ranitidine tablet

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:15127-340

Route of Administration ORAL

# Active Ingredient/Active Moiety

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)

Ingredient Name

Basis of Strength

KANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10 YB7)

RANITIDINE

150 mg

Inactive Ingredients				
Ingredient Name	Strength			
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28 OL 1HH48)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
TALC (UNII: 7SEV7J4R1U)				

Product Characteristics				
Color	pink	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	9 R	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:15127-340-24	24 in 1 CARTON			
1		1 in 1 BLISTER PACK			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200536	03/30/2012	

# Labeler - Select Brand (043562370)

Establishment				
Name	Address	ID/FEI	Business Operations	
Shasun Pharmaceuticals Limited		915786829	manufacture(15127-340)	

Revised: 10/2012 Select Brand