

**RANITIDINE HYDROCHLORIDE- ranitidine hydrochloride tablet**  
**Gericare Pharmaceuticals**

-----  
**MAXIMUM STRENGTH**  
**Ranitidine Tablets USP, 150 MG**

**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 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 a doctor if**

- your heartburn continues or worsens

- you need to take this product for more than 14 days.

## **OTC - PREGNANCY OR BREAST FEEDING**

ask a health professional before use.

## **OTC - KEEP OUT OF REACH OF CHILDREN**

**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)
- children under 12 years: ask a doctor

## **Other information**

- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

## **Inactive ingredients**

colloidal silicon dioxide, ferric oxide red, glyceryl monostearate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, sodium lauryl sulphate, talc, and titanium dioxide

## **Questions?**

call **1-800-540-3765**

Manufactured in INDIA for:

Gericare Pharmaceuticals,

1650 63 Street, Brooklyn, NY 11204

M.L. No.: TN00002326

Rev. 05/2019

## **Consumer Information Leaflet**

*What you should know about*

### **MAXIMUM STRENGTH**

#### **Ranitidine Tablets USP, 150 mg/ Acid Reducer**

*(Please read all of this information before taking MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg. Save this leaflet for future reference.)*

**What are MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg?**

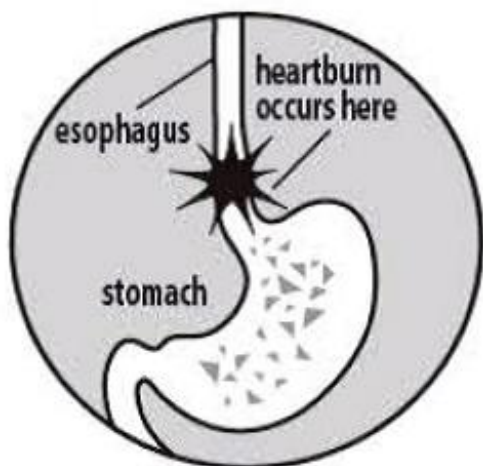
- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg contains 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

### ***Excellent Safety Record***

- The ingredient in MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg has been taken safely with many frequently prescribed medications.
- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg are sodium and sugar free.

### ***What symptoms does MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg relieve and prevent?***

- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg relieves and prevents heartburn associated with acid indigestion and sour stomach.
- Certain foods or beverages, and even lying down to sleep can cause heartburn associated with acid indigestion and sour stomach. It is normal for the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause burning pain and discomfort.



### ***How should I take MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg?***

- 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.
- This medicine can be used up to twice daily (do not take more than 2 tablets in 24 hours).
- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg should not be given to children under 12 years old unless directed by a doctor.
- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers

### ***How do MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg work?***

- MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg reduces the production of stomach acid. This is what makes MAXIMUM STRENGTH Ranitidine Tablets USP, 150 mg different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

### ***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, even some fruits and vegetables
- Eat slowly and do not eat big 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

***When should I see a doctor?***

- **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 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.

**Questions?** call at **1-800-540-3765**

**Manufactured by:**

Vivimed Life Sciences Private Limited,  
Plot No. 101, 102, 107 & 108,  
SIDCO Pharmaceutical Complex, Alathur,  
Kanchipuram – 603 110, Tamilnadu, India.

**Distributed by:**

Gericare Pharmaceuticals,  
1650 63 Street, Brooklyn, NY 11204

Rev. 05/2020

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**NDC 57896-713-50**

MAXIMUM STRENGTH

**Ranitidine Tablets, USP**

**150 mg**

**ACID REDUCER**

***PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach***

*5000 tablets*

*Gericare*

This is bulk pack for repackaging only		Each film-coated tablet contains Ranitidine 150 mg (as ranitidine hydrochloride USP, 168 mg). Store at 20° to 25°C (68° to 77°F). Avoid excessive heat or humidity. M.L.No. TN00002326
<b>NDC 57896-713-50</b>		
MAXIMUM STRENGTH <b>Ranitidine Tablets, USP</b>		
<b>150 mg</b>		
<b>ACID REDUCER</b>		
<i>PREVENTS &amp; RELIEVES HEARTBURN Associated with and indigestion and sour stomach</i>		
5000 Tablets	Film-Coated	
<b>FOR REPACKAGING ONLY</b>		
		<b>Manufactured By:</b> Vivimed Life Sciences Private Limited, Plot No. 101, 102, 107 & 108, SIDCO Pharmaceutical Complex, Alathur, Kanchipuram – 603 110, TN, India
		<b>Repackaged By:</b> Gericare Pharmaceuticals, 1650-63 Street, Brooklyn, NY 11204 72000475-00      Rev. 10/2018
		LOT: EXP.:

NDC 57896-713-03

MAXIMUM STRENGTH

**Ranitidine Tablets, USP**


**150 mg**

**ACID REDUCER**

***PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach***

*30 tablets*

*Gericare*



NDC 57896-713-03

New Formula!

Meets FDA standards for NDMA

MAXIMUM STRENGTH

ACID REDUCER

RANITIDINE USP, 150 MG

PREVENTS & RELIEVES HEARTBURN

Associated with Acid Indigestion and Sour Stomach

Compare to active ingredient

ZANTAC 150\*\*\*

30 Tablets

\* This product has been laboratory tested to meet FDA standards for NDMA (N-nitrosodimethylamine)

Ranitidine reduces the production of stomach acid. This is different than antacids which neutralize acid already in the stomach, but do not reduce the production of acid.

**Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

**Drug Facts** (See back of label for important information)

**Active ingredient (in each tablet)** Purpose  
Ranitidine 150 mg (as Ranitidine HCl USP, 168 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 • kidney disease

**Ask a doctor or pharmacist before use if you are** taking a prescription drug. Acid reducers may interact with certain prescription drugs.

\*\*This product is not manufactured or distributed by the owner of the registered trademark Zantac 150®.  
Dist. By: Qualitabs Inc.  
Brooklyn, NY 11204  
1-800-540-3765  
Product of India

REV 1019S



3 57896 77003 7

PEEL HERE FOR MORE INFORMATION

**Drug Facts (continued)**  
**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**  
• swallow tablet with a glass of water  
• adults and children 12 years and over:  
• to relieve symptoms take 1 tablet  
• to prevent symptoms take 1 tablet **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** • store at 20° - 25°C (68°F - 77°F) • avoid excessive heat or humidity  
• this product is sodium and sugar free

**Inactive ingredients**  
colloidal silicon dioxide, ferric oxide red, glyceryl monostearate, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, sodium lauryl sulphate, talc, titanium dioxide

**Questions?** Call 1-800-540-3765  
**Tips for Managing Heartburn**  
Certain foods or beverages, and even lying down to sleep, can cause heartburn. It is normal for the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause pain and discomfort.  
• 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 big 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.

**STOP PEELING**

RANITIDINE HYDROCHLORIDE

ranitidine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-713
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10 YB7)		RANITIDINE	150 mg

Inactive Ingredients	
Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP)	

TALC (UNII: 7SEV7J4R1U)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
Product Characteristics				
Color	PINK (pink to light pink)	Score	no score	
Shape	PENTAGON (5 SIDED)	Size	10mm	
Flavor		Imprint Code	V;31	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-713-50	5000 in 1 BAG; Type 0: Not a Combination Product	08/02/2019	
2	NDC:57896-713-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA209161		08/02/2019	

**Labeler** - Gericare Pharmaceuticals (611196254)

**Registrant** - Strides Pharma Global Pte. Ltd. (659220961)

## Establishment

Name	Address	ID/FEI	Business Operations
Vivimed Life Sciences Private Limited		860477684	ANALYSIS(57896-713) , MANUFACTURE(57896-713)

Revised: 5/2020

Gericare Pharmaceuticals