

RANITIDINE- ranitidine tablet, film coated
Gericare Pharmaceuticals

REGULAR STRENGTH
Ranitidine Tablets USP, 75 mg

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

- 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.

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

- 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, ferric oxide yellow, 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

REGULAR STRENGTH

Ranitidine Tablets USP, 75 mg/ Acid Reducer

(Please read all of this information before taking Ranitidine Tablets USP, 75 mg. Save this leaflet for future reference.)

What are Ranitidine Tablets USP, 75 mg?

- Ranitidine Tablets USP, 75 mg contains 75 mg of ranitidine (as ranitidine hydrochloride USP, 84

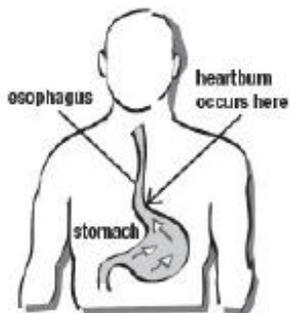
mg), a medicine that doctors have prescribed more than 200 million times worldwide.

Excellent Safety Record

- Ranitidine Tablets USP, 75 mg has been used safely and effectively for years as an over-the-counter.
- Ranitidine Tablets USP, 75 mg are sodium and sugar free.

What symptoms does Ranitidine Tablets USP, 75 mg relieve and prevent?

- Ranitidine Tablets USP, 75 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 Ranitidine Tablets USP, 75 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).
- Do not chew tablet.
- Ranitidine Tablets USP, 75 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

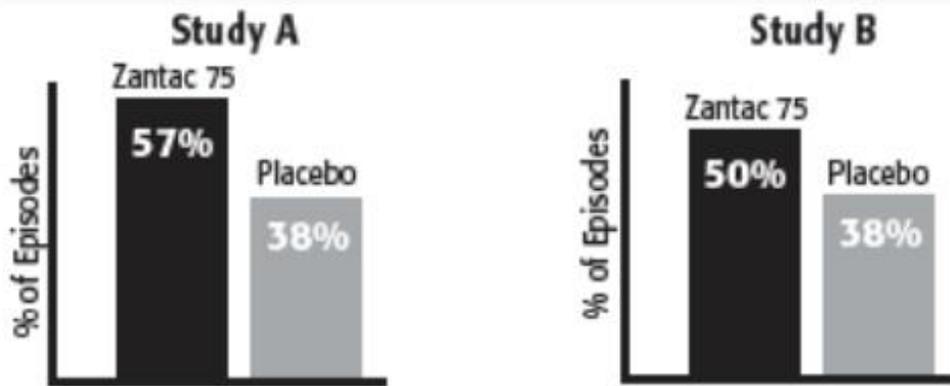
How does Ranitidine Tablets USP, 75 mg work?

- Ranitidine Tablets USP, 75 mg reduces the production of stomach acid. This is what makes Ranitidine Tablets USP, 75 mg different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

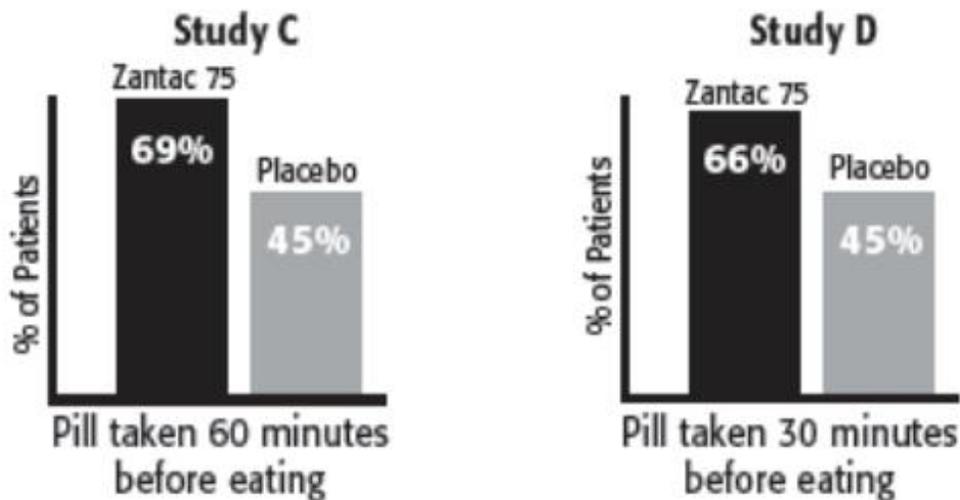
Additional tips for managing heartburn

- 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

Percent of Heartburn Episodes Relieved



Percent of Patients with Prevention or Reduction of Heartburn Symptoms



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 **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 57896-712-01

REGULAR STRENGTH

Ranitidine Tablets, USP

75 mg

ACID REDUCER

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

10000 film coated tablets

Gericare

This is bulk pack for repackaging only

NDC 57896-712-01

REGULAR STRENGTH

Ranitidine Tablets, USP

75 mg

ACID REDUCER

*PREVENTS & RELIEVES HEARTBURN
Associated with and indigestion and sour
stomach*

10000 Tablets

Film-Coated

FOR REPACKAGING ONLY

Each film-coated tablet contains

Ranitidine 75 mg (as ranitidine
hydrochloride USP, 84 mg).

Store at 20° to 25°C (68° to 77°F).

Avoid excessive heat or humidity.

M.L.No. TN00002326

Manufactured By:

Vivimed Life Sciences Private Limited,

Plot No. 101, 102, 107 & 108,

SIDCO Pharmaceutical Complex,

Alathur, Kanchipuram – 603 110, TN,

India

Repackaged By:

Gericare Pharmaceuticals,

1650 63 Street, Brooklyn, NY 11204

72000444-00

Rev. 09/2018

LOT:

EXP.:

NDC 57896-712-03

REGULAR STRENGTH

Ranitidine Tablets, USP

75 mg

ACID REDUCER

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

30 film coated tablets

Gericare

HEALTH STAR NDC 57896-712-03

New Formula!
Meets FDA standards for NDMA*

REGULAR STRENGTH
ACID REDUCER
RANITIDINE USP, 75 MG
PREVENTS & RELIEVES HEARTBURN
Associated with Acid Indigestion and Sour Stomach

Compare to active ingredient in ZANTAC 75***
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 75 mg (as Ranitidine HCl USP, 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

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• 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 75®.
Dist. By: Qualitabs Inc.
Brooklyn, NY 11204
1-800-540-3765
Product of India

REV 1019S

3 57896 176503 3
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
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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, ferric oxide yellow, 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

ranitidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-712
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

TALC (UNII: 7SEV7J4R1U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	PINK (peach to light peach)	Score	no score
Shape	PENTAGON (5 SIDED)	Size	8mm
Flavor		Imprint Code	V;30
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-712-01	10000 in 1 BAG; Type 0: Not a Combination Product	08/02/2019	
2	NDC:57896-712-03	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	ANDA209160	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(57896-712) , MANUFACTURE(57896-712)

Revised: 5/2020

Gericare Pharmaceuticals