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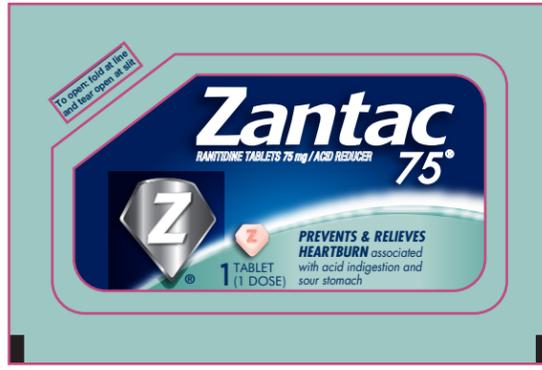
Product: Zantac 75®

Component: 75 mg 1ct Pouch

Date: July 2014

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FRONT



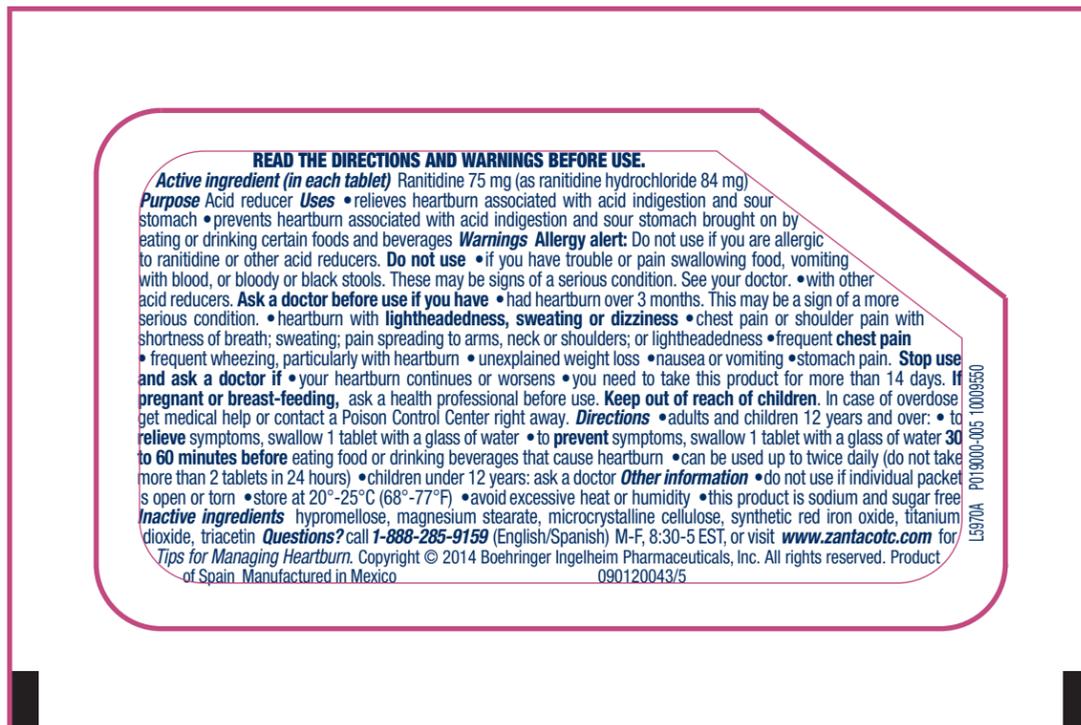
BACK



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FRONT



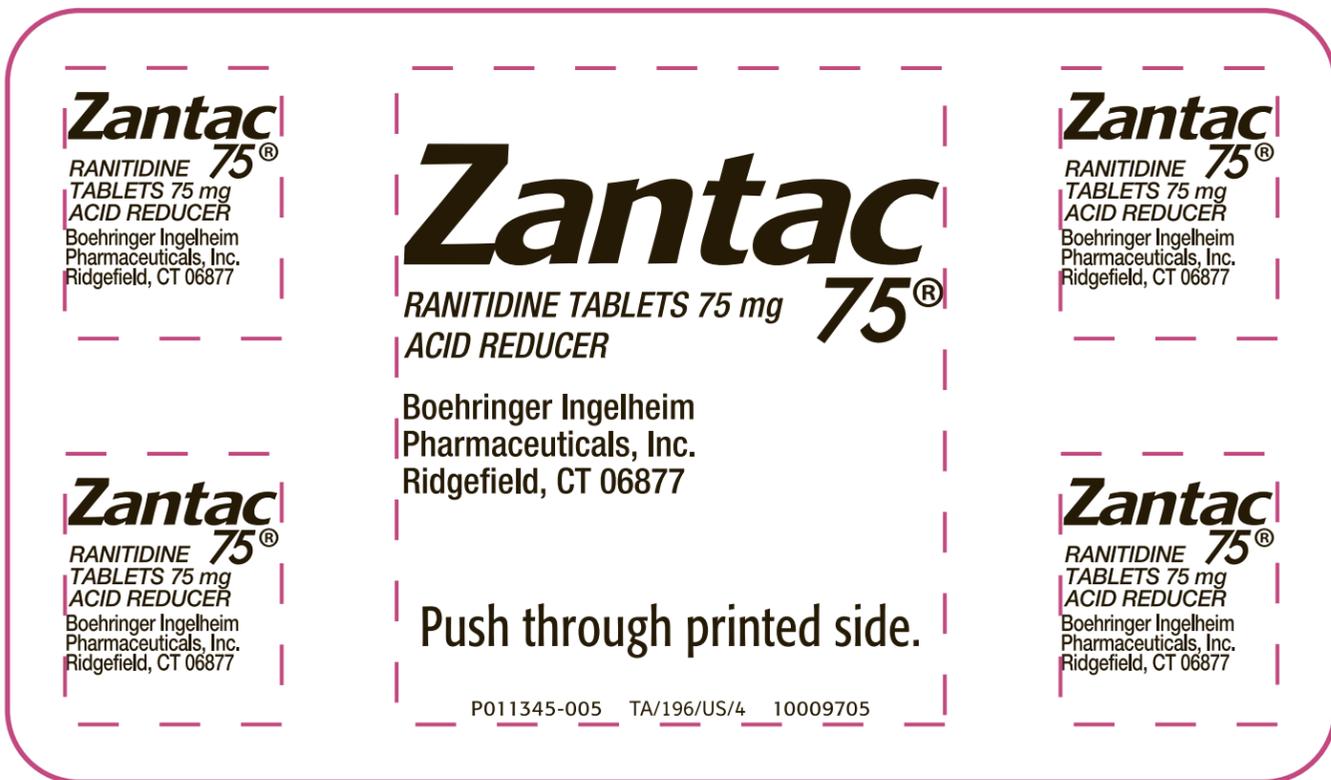
BACK

(b) (4)

 Boehringer Ingelheim
Copy for NDA Submission
Product: Zantac 75®
Component: 75 mg 4ct Blister Foil Label
Date: July 2014



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200%



Boehringer
Ingelheim

Copy for NDA Submission

Product:
Zantac 75®

Component:
**75 mg 4ct
Blister Carton**

Date:
January 2015

LOT

EXP

Drug Facts (continued)

Inactive Ingredients
hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, triacetin

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

Drug Facts

Active ingredient (in each tablet)
Ranitidine 75 mg (as ranitidine hydrochloride 84 mg).....Acid reducer

Purpose
• 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
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
• unexplained weight loss
• nausea or vomiting
• stomach pain

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
• prevent symptoms, swallow 1 tablet with a glass of water
• 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
• avoid excessive heat or humidity
• this product is sodium and sugar free

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Boehringer Ingelheim
Division of Boehringer-Ingelheim
Rohde and Chas. Meibohm
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Made in Spain

090320944/4
CT6118B

Zantac 75
Ranitidine Tablets 75 mg / Acid Reducer

ZANTAC does not supply store brands

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

P011057-005

Zantac

Ranitidine Tablets 75 mg / Acid Reducer **75**

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

4 TABLETS
(4 DOSES)

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Reference ID: 3695815

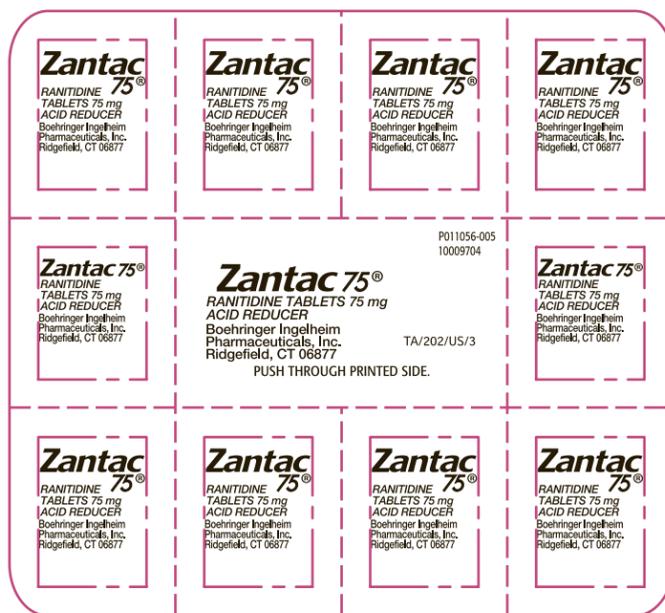


**Copy for NDA
Submission**

Product:
Zantac 75[®]

Component:
**75 mg 10ct
Blister Foil Label**

Date:
July 2014



100%



200%



Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®

Component:
75 mg 10ct Blister Carton

Date:
January 2015

Drug Facts (continued)

Questions? call 1-888-285-9199 (English/Spanish) or visit www.zantac.com
M-F, 8:30 - 5 EST.

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Pharmaceuticals, Inc., Ridgefield, CT 06877
Product Division of Boehringer Ingelheim

Drug Facts

Active ingredient (in each tablet)
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 **lightheadness, sweating or dizziness**
• chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadness
• 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
• adults and children 12 years and over:
• 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
• do not use if individual blister unit is open or torn
• avoid excessive heat or humidity
• this product is sodium and sugar free
• store at 20°-25°C (68°-77°F)

Inactive ingredients hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, triacetin

LOT

EXP

Zantac
Ranitidine Tablets 75 mg / Acid Reducer

75

Zantac
Ranitidine Tablets 75 mg / Acid Reducer

75

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

10 TABLETS (10 DOSES)

P011060-006

8 1421 03003 8

503



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Copy for NDA Submission

Product:
Zantac 75®

Component:
**75 mg 60ct
Bottle Label**

Date:
July 2014

Warnings 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.

Bottle sealed with printed foil under cap. Do not use if foil is open or torn.

Zantac
RANITIDINE TABLETS
75 mg / ACID REDUCER **75®**

60
TABLETS
(60 DOSES)

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

Directions • adults and children 12 years and over: • to relieve 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. **Questions?** call 1-888-285-9159 (English/Spanish) M - F, 8:30 - 5 EST, or visit www.zantacotc.com Copyright © 2014, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. All rights reserved. 10009595 4/14 001 P033123-001

090330988/1

LOT

EXP

70

100%

Warnings 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.

Bottle sealed with printed foil under cap. Do not use if foil is open or torn.

Zantac
RANITIDINE TABLETS
75 mg / ACID REDUCER **75®**

60
TABLETS
(60 DOSES)

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

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. **Questions?** call 1-888-285-9159 (English/Spanish) M - F, 8:30 - 5 EST, or visit www.zantacotc.com Copyright © 2014, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. All rights reserved. 10009595 4/14 001 P033123-001

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Ingelheim

Copy for NDA Submission

Product:
Zantac 75®

Component:
**75 mg 60ct
Bottle Carton**

Date:
January 2015



Zantac
Ranitidine Tablets 75 mg/Acid Reducer
75

60 TABLETS
(60 DOSES)

PREVENTS & RELIEVES
HEARTBURN associated with
acid indigestion and sour stomach



808

090320949/5
CT6123A
P011066-007

Zantac
Ranitidine Tablets 75 mg/Acid Reducer
75

Zantac
Ranitidine Tablets 75 mg/Acid Reducer
75

Zantac
Ranitidine Tablets 75 mg/Acid Reducer
75

60 TABLETS
(60 DOSES)



6 81421 03006 9

Drug Facts

Active ingredient (in each tablet) Ranitidine 75 mg (as ranitidine hydrochloride 84 mg)	Purpose Acid reducer
Uses	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • adults and children 12 years and over: <ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • do not use if printed foil under bottle cap is open or torn • avoid excessive heat or humidity 	<ul style="list-style-type: none"> • store at 20°-25°C (68°-77°F) • this product is sodium and sugar free

Zantac
Ranitidine Tablets 75 mg/Acid Reducer
75

60 TABLETS
(60 DOSES)

LOT
EXP

ZANTAC does not supply store brands

Drug Facts (continued)

Inactive ingredients hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red 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.

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Product of Spain. Manufactured in Mexico.

(b) (4)



Copy for NDA Submission

Product:
Zantac 75®

Component:
**75 mg 80ct
Bottle Label**

Date:
July 2014

Warnings 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.

Bottle sealed with printed foil under cap. Do not use if foil is open or torn.

Zantac
RANITIDINE TABLETS
75 mg / ACID REDUCER
75®

80
TABLETS
(80 DOSES)

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

Directions • adults and children 12 years and over: • to relieve 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. **Questions?** call 1-888-285-9159 (English/Spanish) M-F, 8:30-5 EST, or visit www.zantacotc.com Copyright © 2014, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. All rights reserved. 10009599 4/14 001 P033124-001

090330989/1

LOT

EXP

84

100%

Warnings 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.

Bottle sealed with printed foil under cap. Do not use if foil is open or torn.

Zantac
RANITIDINE TABLETS
75 mg / ACID REDUCER
75®

80
TABLETS
(80 DOSES)

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

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. **Questions?** call 1-888-285-9159 (English/Spanish) M-F, 8:30-5 EST, or visit www.zantacotc.com Copyright © 2014, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. All rights reserved. 10009599 4/14 001 P033124-001

LOT

EXP

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84

200%

(b) (4)



Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®

Component:
**75 mg 80ct
Bottle Carton**

Date:
January 2015

80 TABLETS (80 DOSES)

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

Zantac 75® Ranitidine Tablets 75 mg / Acid Reducer

55

090320950/5
CT16125A
P011068-007

Zantac 75® Ranitidine Tablets 75 mg / Acid Reducer

80 TABLETS (80 DOSES)

Zantac 75® Ranitidine Tablets 75 mg / Acid Reducer

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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)
- children under 12 years: ask a doctor

Other information

- do not use if printed foil under bottle cap is open or torn • store at 20°-25°C (68°-77°F)
- avoid excessive heat or humidity • this product is sodium and sugar free

Zantac 75® Ranitidine Tablets 75 mg / Acid Reducer

80 TABLETS (80 DOSES)

LOT
EXP

ZANTAC does not supply store brands

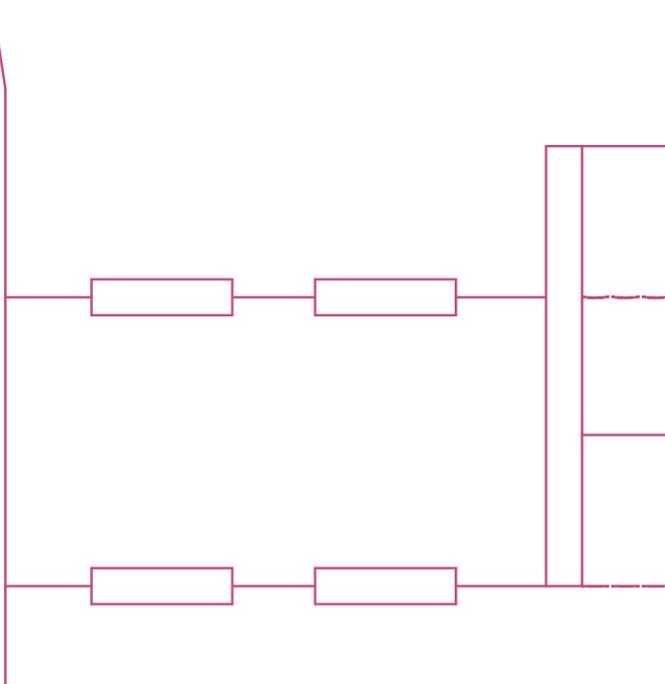
Drug Facts (continued)

Inactive ingredients hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red 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.

Boehringer Ingelheim Consumer Health Care Products
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 Product of Spain. Manufactured in Mexico.



(b) (4)

**Copy for NDA
Submission**

Product:
Zantac 75®

Component:
**75 mg
Consumer Leaflet**

Date:
July 2014

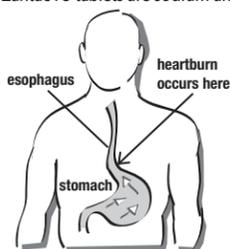


What you should know about

Zantac
RANITIDINE TABLETS 75 mg 75®
ACID REDUCER

(Please read all of this information before taking Zantac 75. Save this leaflet for future reference.)

- Zantac 75 contains 75 mg of ranitidine (as ranitidine hydrochloride, 84 mg), a medicine that doctors have prescribed more than 200 million times worldwide.
- Zantac 75 has been used safely and effectively for years as an over-the-counter medication.
- Zantac 75 tablets are sodium and sugar free.



• Zantac 75 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 or 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.

- 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).

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

090340239/5

What is Zantac 75?

Excellent Safety Record

What symptoms does Zantac 75 relieve and prevent?

How should I take Zantac 75?

How does Zantac 75 work?

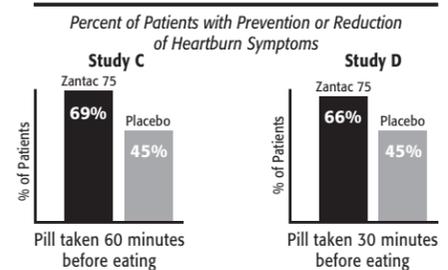
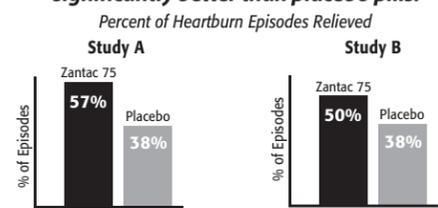
Additional tips for managing heartburn

Clinical studies prove Zantac 75 is effective in relieving ...

... and preventing heartburn.

When should I see a doctor?

In clinical studies, Zantac 75 was significantly better than placebo pills.



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

BOTTLES: Bottle is sealed with printed foil under cap. Do not use if foil is open or torn.

BLISTERS: Do not use if the individual blister unit is open or torn.

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