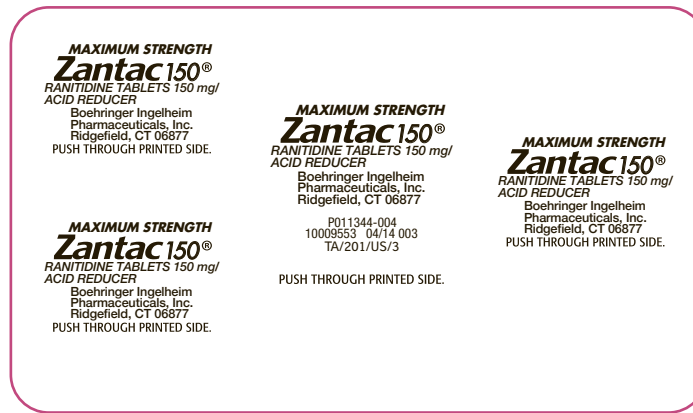
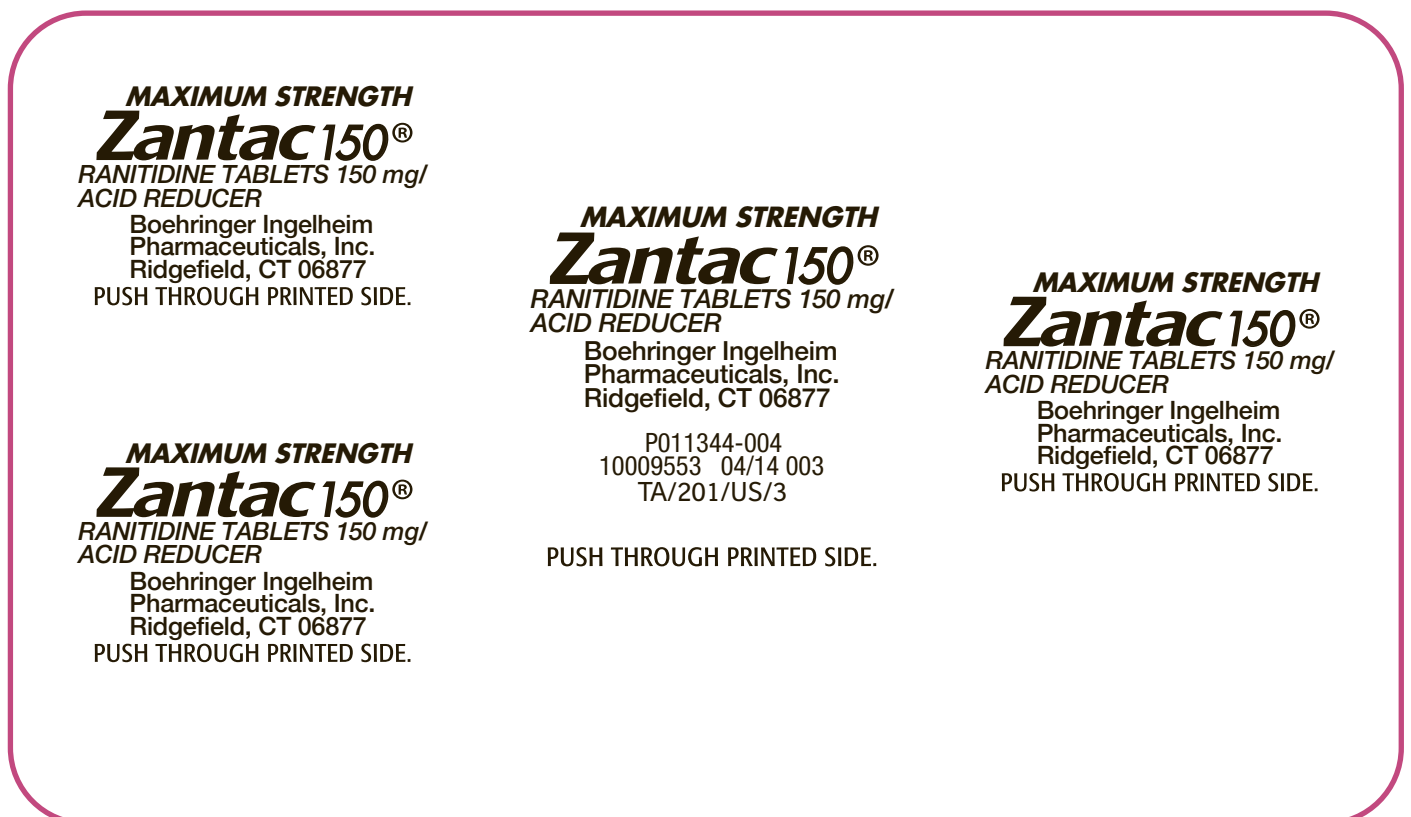

 Boehringer Ingelheim
Copy for NDA Submission
Product: Zantac 150®
Component: 150 mg 3ct Blister Foil Label
Date: February 2016



100%



200%

 Boehringer Ingelheim
Copy for NDA Submission
Product: Zantac 150®
Component: 150 mg Consumer Leaflet
Date: February 2016



What you should know about
MAXIMUM STRENGTH
Zantac
RANITIDINE TABLETS 150 mg
ACID REDUCER **150®**

(Please read all of this information before taking MAXIMUM STRENGTH Zantac 150.
Save this leaflet for future reference.)

**What is
MAXIMUM STRENGTH
Zantac 150?**

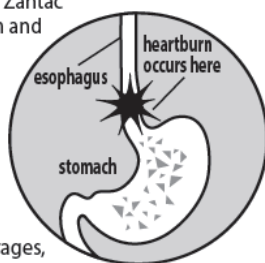
- MAXIMUM STRENGTH Zantac 150 contains 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

**Excellent Safety
Record**

- The ingredient in MAXIMUM STRENGTH Zantac 150, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 has been taken safely with many frequently prescribed medications.

**What symptoms does
MAXIMUM STRENGTH
Zantac 150 relieve
and prevent?**

- MAXIMUM STRENGTH Zantac 150 tablets are sodium and sugar free.
- MAXIMUM STRENGTH Zantac 150 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
Zantac 150?**

- 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 Zantac 150 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

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**How does
MAXIMUM STRENGTH
Zantac 150 work?**

MAXIMUM STRENGTH Zantac 150 reduces the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 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
 - if you have kidney disease, except under the advice and supervision of a doctor
- **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 printed foil is open or torn.

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

FOIL PACKET: Do not use if the individual foil packet is open or torn.


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 Boehringer Ingelheim
Copy for NDA Submission
Product: Zantac 75®
Component: 75 mg 4ct Blister Carton
Date: February 2016

Regular Strength

Zantac

Ranitidine Tablets 75 mg / Acid Reducer

75



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

**4 TABLETS
(4 DOSES)**

ZANTAC does not supply store brands

6 81421 03002 1

090218271
P09751-001
C07610
118 001

Drug Facts

Active ingredient (in each tablet) Ranitidine 75 mg (as ranitidine hydrochloride 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
- 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.

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)
- Keep out of reach of children. Do not use if the seal is broken.
- children under 12 years: ask a doctor.

Other information

- do not use if individual blister unit is open or torn
- store at 20-25°C (68-77°F)
- this product is sodium and sugar free
- a void excessive heat or humidity

LOT

EXP

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

FDA STANDARD FORMAT COPY

STANDARD FORMAT/ HELVETICA NEUE 100% SCALE

DRUG FACTS – 9.1 PT HELVETICA NEUE BOLD CONDENSED ITALIC

DRUG FACTS (continued) – 9.1 PT HELVETICA NEUE BOLD CONDENSED ITALIC

HEADINGS – 8 PT HELVETICA NEUE BOLD CONDENSED ITALIC

SUBHEADS – 6/6.25 PT HELVETICA NEUE BOLD CONDENSED

ALL SMALL TEXT – 6/6.25 PT HELVETICA NEUE CONDENSED


HEAVY RULE – 2.5 PT

LIGHT RULE – .5 PT

HORIZONTAL SCALE – 85%

BULLETS – 5 PT

MM ■ 3/64" -Gap (Border -type)

 **Boehringer
Ingelheim**

**Copy for NDA
Submission**

Product:
Zantac 75®

Component:
**75 mg
Consumer Leaflet**

Date:
February 2016

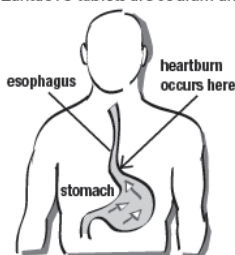


What you should know about
Regular Strength

Zantac
Ranitidine Tablets 75 mg
Acid Reducer **75®**

(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).

- Do not chew tablet

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

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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?

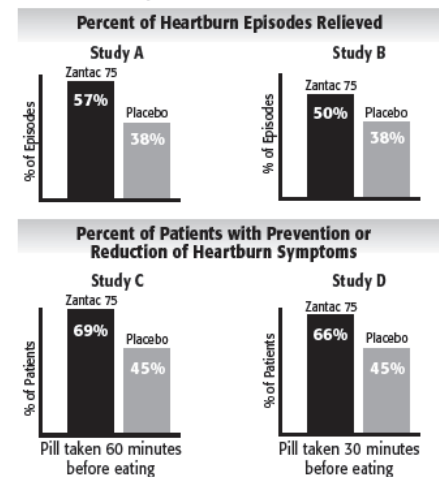
Additional tips for managing heartburn

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

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/s/

KAREN M MAHONEY
07/27/2016