Boehringer Ingelheim

Copy for NDA Submission

Product:

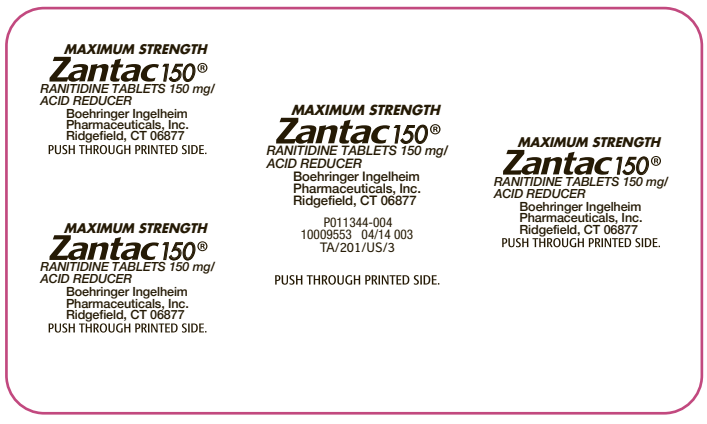
Zantac 150®

Component:

150 mg 3ct
Blister Foil Label

Date:

February 2016



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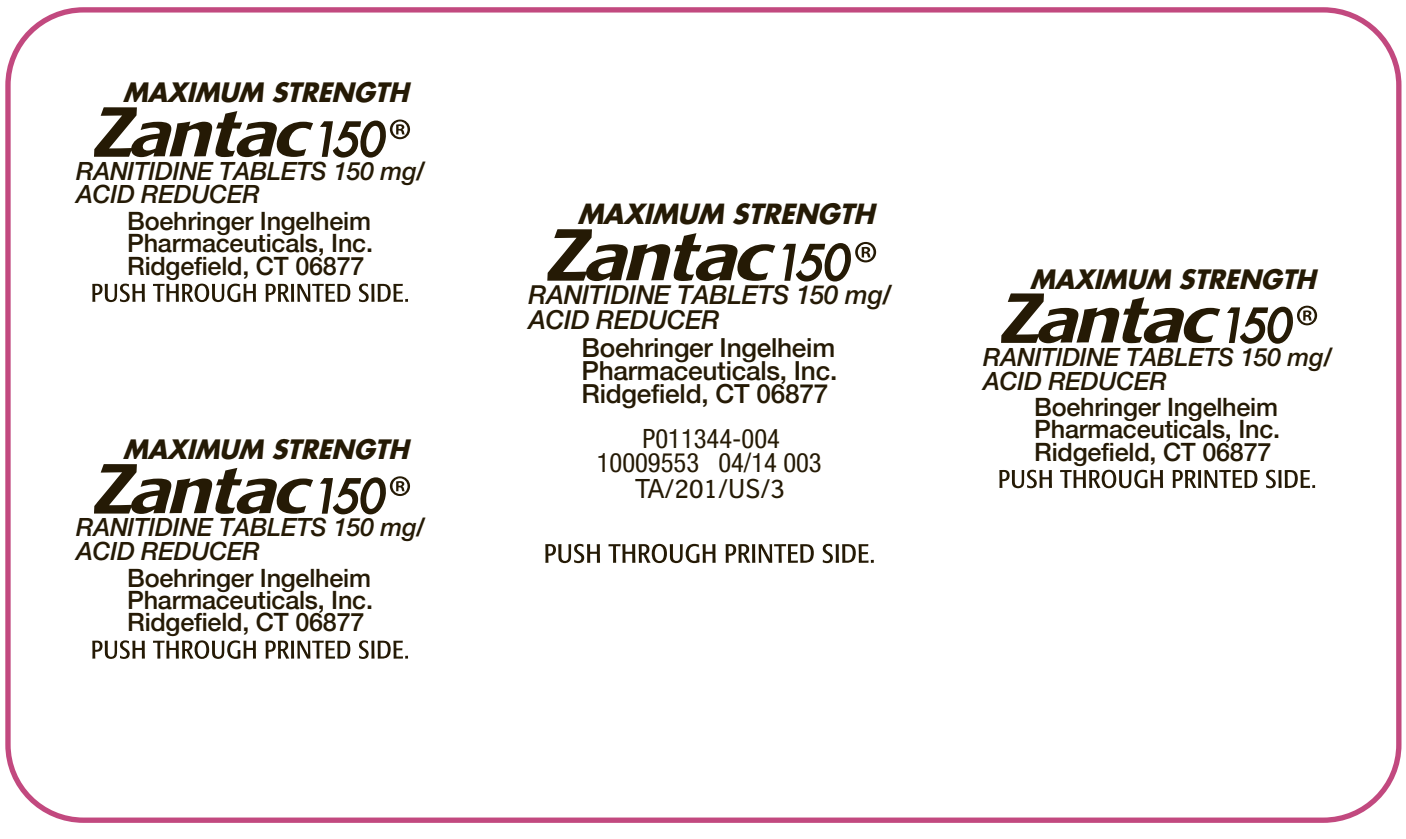

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Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 150®

Component:
150 mg 3ct
Blister Carton

Date:
February 2016

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 150®

Component:
150 mg Consumer Leaflet

Date:
February 2016

Boehringer Ingelheim

What you should know about MAXIMUM STRENGTH Zantac® 150

RANITIDINE TABLETS 150 mg
ACID REDUCER

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

What is MAXIMUM STRENGTH Zantac 150?

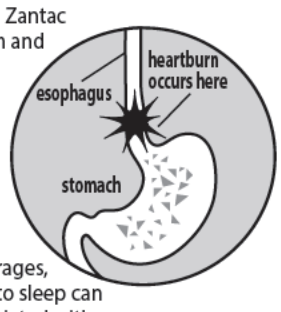
- MAXIMUM STRENGTH Zantac 150 contains 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

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

What symptoms does MAXIMUM STRENGTH Zantac 150 relieve and prevent?

- 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

- **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

When should I see 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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Copy for NDA Submission

Product:

Zantac 75®

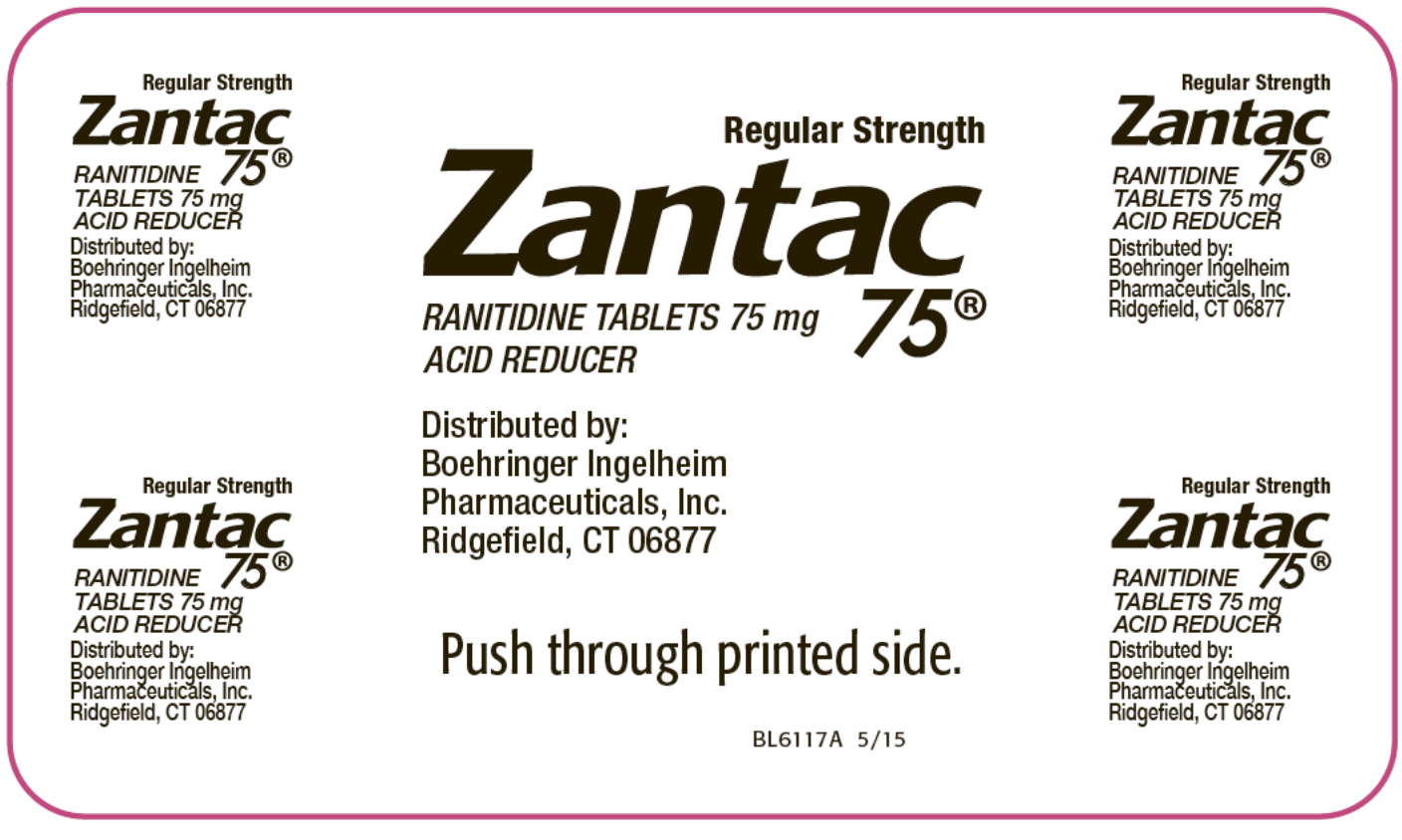
Component:

75 mg 4ct
Blister Foil Label

Date:

February 2016

100%



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Copy for NDA Submission

Product:
Zantac 75®

Component:
75 mg 4ct
Blister Carton

Date:
February 2016

FDA STANDARD FORMAT COPY
STANDARD FORMAT/ HELVETICA NEUE 100% SCALE

DRUG FACTS –9.1 PT HELVETICA NEUE BOLD CONDENSED ITALIC
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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

Boehringer Ingelheim

What you should know about

Regular Strength

Zantac 75®

Ranitidine Tablets 75 mg
Acid Reducer

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

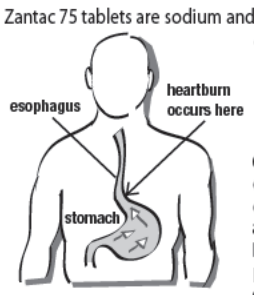
What is Zantac 75?

- Zantac 75 contains 75 mg of ranitidine (as ranitidine hydrochloride, 84 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

Excellent Safety Record

- Zantac 75 has been used safely and effectively for years as an over-the-counter medication.
- Zantac 75 tablets are sodium and sugar free.

What symptoms does Zantac 75 relieve and prevent?



- 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.

How should I take Zantac 75?

- 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.

How does Zantac 75 work?

- **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.

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

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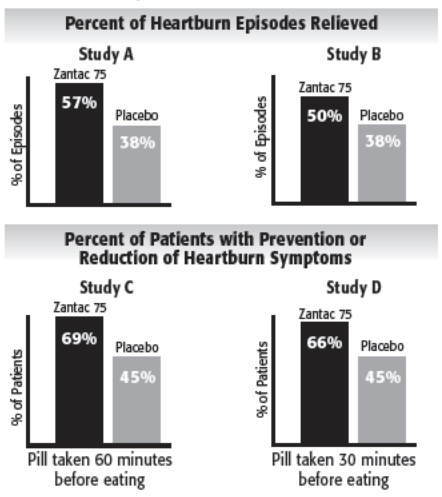
Clinical studies prove Zantac 75 is effective in relieving ...

... and preventing heartburn.

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



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
- **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.

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/s/

KAREN M MAHONEY
07/27/2016