Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
1ct Foil Packet

Date:
December 2015

100%

FRONT

BACK

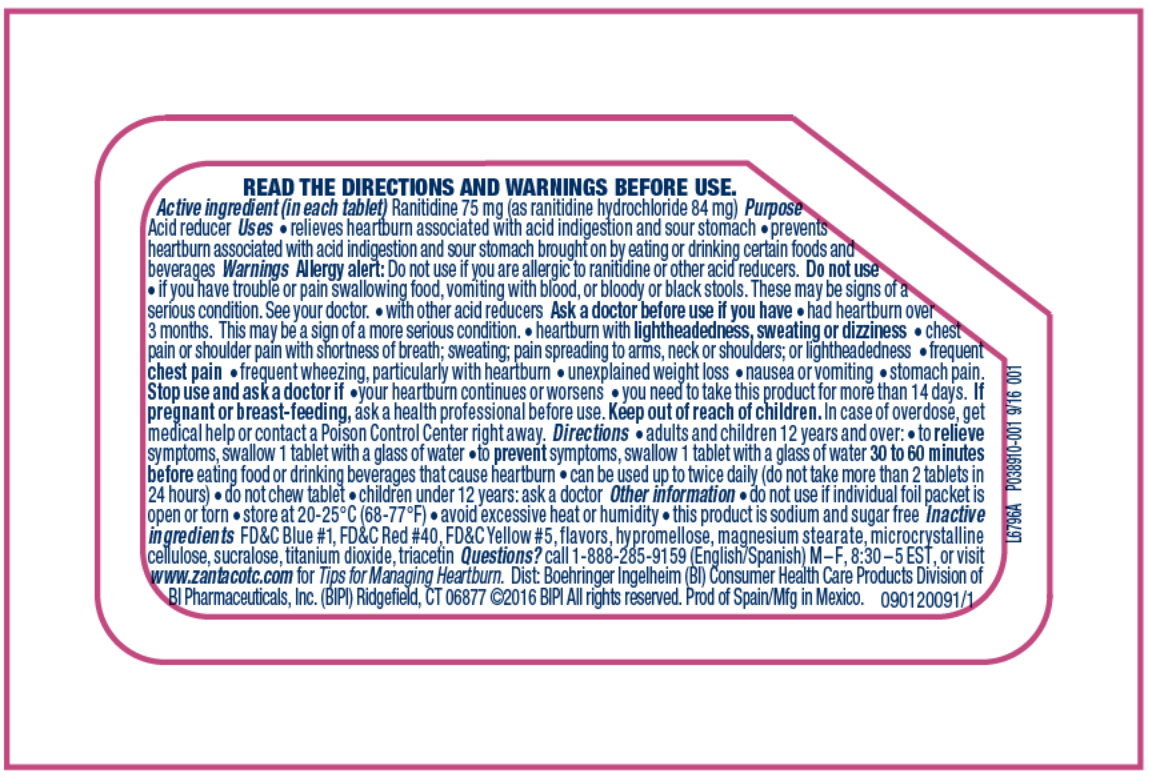
READ THE DIRECTIONS AND WARNINGS BEFORE USE.

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** • 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) • do not chew tablet • children under 12 years: ask a doctor ***Other information*** • do not use if individual foil packet is open or torn • store at 20-25°C (68-77°F) • avoid excessive heat or humidity • this product is sodium and sugar free ***Inactive ingredients*** FD&C Blue #1, FD&C Red #40, FD&C Yellow #5, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, sucralose, titanium dioxide, triacetin ***Questions?*** call 1-888-285-9159 (English/Spanish) M–F, 8:30–5 EST, or visit ***www.zantacotc.com*** for *Tips for Managing Heartburn.* Dist: Boehringer Ingelheim (BI) Consumer Health Care Products Division of BI Pharmaceuticals, Inc. (BIPI) Ridgefield, CT 06877 ©2016 BIPI All rights reserved. Prod of Spain/Mfg in Mexico. 090120091/1

L67964 P038910-001 9/16 001

200%

FRONT



READ THE DIRECTIONS AND WARNINGS BEFORE USE.

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** • 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) • do not chew tablet • children under 12 years: ask a doctor ***Other information*** • do not use if individual foil packet is open or torn • store at 20-25°C (68-77°F) • avoid excessive heat or humidity • this product is sodium and sugar free ***Inactive ingredients*** FD&C Blue #1, FD&C Red #40, FD&C Yellow #5, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, sucralose, titanium dioxide, triacetin ***Questions?*** call 1-888-285-9159 (English/Spanish) M–F, 8:30–5 EST, or visit ***www.zantacotc.com*** for *Tips for Managing Heartburn.* Dist: Boehringer Ingelheim (BI) Consumer Health Care Products Division of BI Pharmaceuticals, Inc. (BIPI) Ridgefield, CT 06877 ©2016 BIPI All rights reserved. Prod of Spain/Mfg in Mexico. 090120091/1

L67964 P038910-001 9/16 001

BACK

FDA NARRATIVE FORMAT COPY

NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE

HEADINGS – 4.4 PT HELVETICA NEUE BOLD CONDENSED ITALIC

SUBHEADS – 4.4 PT HELVETICA NEUE BOLD CONDENSED

ALL SMALL TEXT – 4.4 PT HELVETICA NEUE CONDENSED

HORIZONTAL SCALE – 80%

BULLETS – 4.5 PT

MM ■

Reference ID: 3878015

Boehringer Ingelheim

Copy for NDA Submission

Product:

Zantac 75® Cool Mint

Component:

75 mg Cool Mint 10ct Blister Foil

Date:

July 2015

100%

200%

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
30ct Blister Carton

Date:
September 2015

Reference ID: 3878015

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
40ct Blister Carton

Date:
September 2015

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

DRUG FACTS–10 PT HELVETICA NEUE BOLD CONDENSED ITALIC
DRUG FACTS (continued)–9 PT HELVETICA NEUE BOLD CONDENSED ITALIC
HEADINGS– 8 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 6/6.1 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 6/6.1 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®
Cool Mint

Component:
75 mg Cool Mint
48ct Bottle Label

Date:
September 2015

100%

200%

FDA NARRATIVE FORMAT COPY
NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
HEADINGS– 4.75 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 4.75 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 4.75 PT HELVETICA NEUE CONDENSED
HORIZONTAL SCALE 84%
BULLETS – 4.75 PT
MM ■

Boehringer Ingelheim

Copy for NDA Submission

Product:

Zantac 75®
Cool Mint

Component:

75 mg Cool Mint
48ct Bottle Carton

Date:

September 2015

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) • do not chew tablet
- children under 12 years: ask a doctor

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

Drug Facts (continued)

Inactive ingredients FD&C Blue #1, FD&C Red #40, FD&C Yellow #5, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, sucralose, 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.

Distributed by: Boehringer Ingelheim (BI) Consumer Health Care Products
Division of BI Pharmaceuticals, Inc., Ridgefield, CT 06877
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Product of Spain. Manufactured in Mexico.

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

DRUG FACTS–10 PT HELVETICA NEUE BOLD CONDENSED ITALIC
DRUG FACTS (continued)–9 PT HELVETICA NEUE BOLD CONDENSED ITALIC
HEADINGS– 8 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 6/6.1 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 6/6.1 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®
Cool Mint

Component:
75 mg Cool Mint
60ct Bottle Label

Date:
September 2015

100%

200%

FDA NARRATIVE FORMAT COPY
NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
HEADINGS– 4.75 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 4.75 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 4.75 PT HELVETICA NEUE CONDENSED
HORIZONTAL SCALE 84%
BULLETS – 4.75 PT
MM ■

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
60ct Bottle Carton

Date:
September 2015

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

DRUG FACTS–10 PT HELVETICA NEUE BOLD CONDENSED ITALIC
DRUG FACTS (continued)–9 PT HELVETICA NEUE BOLD CONDENSED ITALIC
HEADINGS– 8 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 6/6.1 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 6/6.1 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)

Reference ID: 3878015

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
72ct Bottle Label

Date:
September 2015

100%

200%

FDA NARRATIVE FORMAT COPY
NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
HEADINGS– 4.75 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 4.75 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 4.75 PT HELVETICA NEUE CONDENSED
HORIZONTAL SCALE 84%
BULLETS – 4.75 PT
MM ■

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
72ct Bottle Carton

Date:
September 2015

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

DRUG FACTS–10 PT HELVETICA NEUE BOLD CONDENSED ITALIC
DRUG FACTS (continued)–9 PT HELVETICA NEUE BOLD CONDENSED ITALIC
HEADINGS– 8 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 6/6.1 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 6/6.1 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)

Reference ID: 3878015

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
80ct Bottle Label

Date:
September 2015

100%

200%

FDA NARRATIVE FORMAT COPY
NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
HEADINGS– 4.75 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 4.75 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 4.75 PT HELVETICA NEUE CONDENSED
HORIZONTAL SCALE 84%
BULLETS – 4.75 PT
MM ■

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
80ct Bottle Carton

Date:
September 2015

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

DRUG FACTS–10 PT HELVETICA NEUE BOLD CONDENSED ITALIC
DRUG FACTS (continued)–9 PT HELVETICA NEUE BOLD CONDENSED ITALIC
HEADINGS– 8 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 6/6.1 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 6/6.1 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)

Reference ID: 3878015

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
96ct Bottle Label

Date:
September 2015

100%

200%

FDA NARRATIVE FORMAT COPY
NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
HEADINGS– 4.75 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 4.75 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 4.75 PT HELVETICA NEUE CONDENSED
HORIZONTAL SCALE 84%
BULLETS – 4.75 PT
MM ■

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
96ct Bottle Carton

Date:
September 2015

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

DRUG FACTS–10 PT HELVETICA NEUE BOLD CONDENSED ITALIC
DRUG FACTS (continued)–9 PT HELVETICA NEUE BOLD CONDENSED ITALIC
HEADINGS– 8 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 6/6.1 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 6/6.1 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)

Reference ID: 3878015

Boehringer Ingelheim

Copy for NDA Submission

Product:

Zantac 75®
Cool Mint

Component:

75 mg Cool Mint
100ct Packet Dispenser

Date:

September 2015

FDA STANDARD FORMAT COPY

STANDARD FORMAT/ HELVETICA NEUE 100% SCALE

DRUG FACTS–9. PT HELVETICA BOLD CONDENSED ITALIC

HEADINGS– 8 PT HELVETICA BOLD CONDENSED ITALIC

SUBHEADS- 6 PT HELVETICA BOLD CONDENSED

ALL SMALL TEXT – 6/6.25 PT HELVETICA NEUE CONDENSED

HEAVY RULE – 2.5 PT

LIGHT RULE –.5 PT

HORIZONTAL SCALE 100%

BULLETS – 5 PT

MM ▬ 3/64" -Gap (Border -type)

Reference ID: 3878015

Boehringer Ingelheim

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Product:
Zantac 75®
Cool Mint

Component:
75 mg Cool Mint
Consumer Leaflet

Date:
July 2015

What you should know about

COOL MINT TABLETS

Zantac 75®

Ranitidine Tablets 75 mg/
Acid Reducer

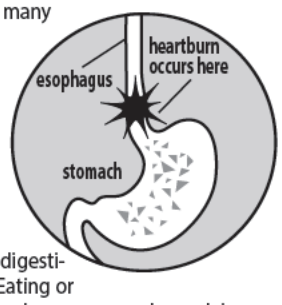
(Please read all of this information before taking Zantac 75 Cool Mint Tablets. Save this leaflet for future reference.)

What are Zantac 75 Cool Mint Tablets?

- Zantac 75 Cool Mint Tablets contain 75 mg of ranitidine (as ranitidine hydrochloride, 84 mg), a medicine that doctors have prescribed more than 200 million times worldwide.
- When swallowed, Zantac 75 Cool Mint Tablets release a cooling sensation in the mouth and throat.

Excellent Safety Record

- The ingredient in Zantac 75 Cool Mint Tablets, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in Zantac 75 Cool Mint Tablets has been taken safely with many frequently prescribed medications.
- Zantac 75 Cool Mint Tablets are sodium and sugar free.



What symptoms do Zantac 75 Cool Mint Tablets relieve and prevent?

- Zantac 75 Cool Mint Tablets relieve and prevent heartburn associated with acid indigestion and sour stomach. Eating or drinking 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 Zantac 75 Cool Mint Tablets?

- 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 Cool Mint Tablets 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 Zantac 75 Cool Mint Tablets work?

- Zantac 75 Cool Mint Tablets reduce the production of stomach acid. This is what makes Zantac 75 Cool Mint Tablets 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
- **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 individual foil packet is open or torn.

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