

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 150®

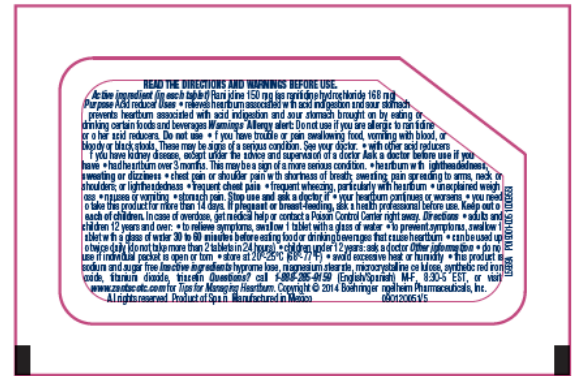
Component:
150 mg 1ct Pouch

Date:
July 2014

100%

FRONT

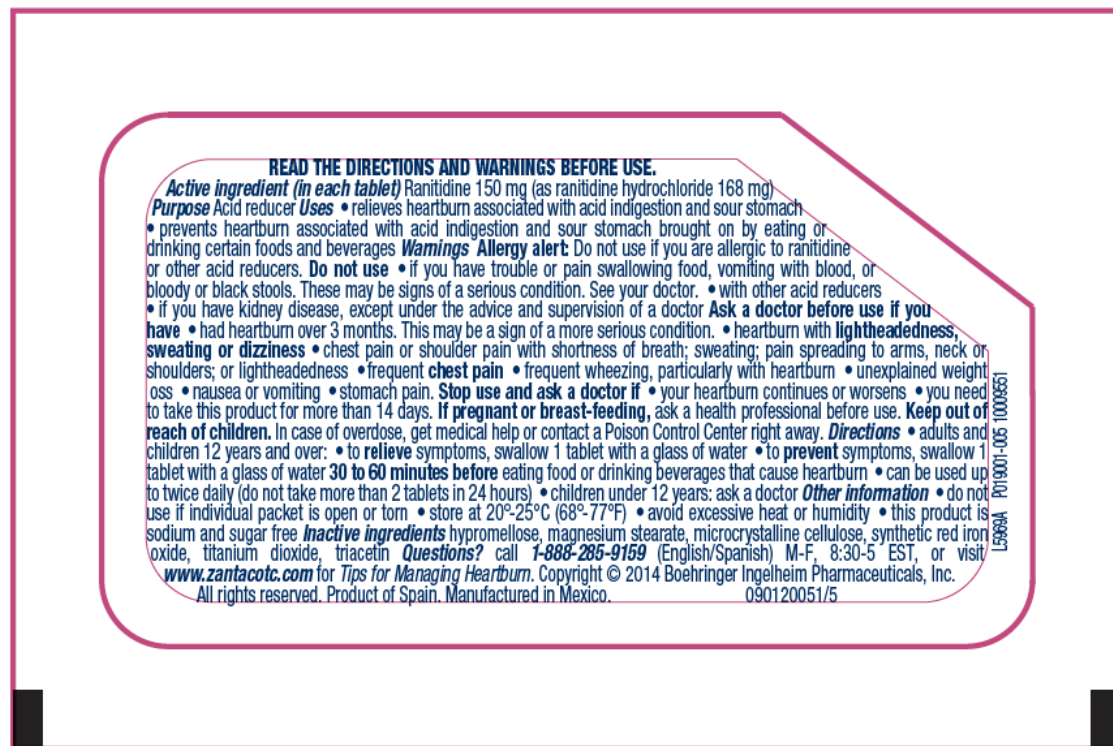
BACK



200%



FRONT



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

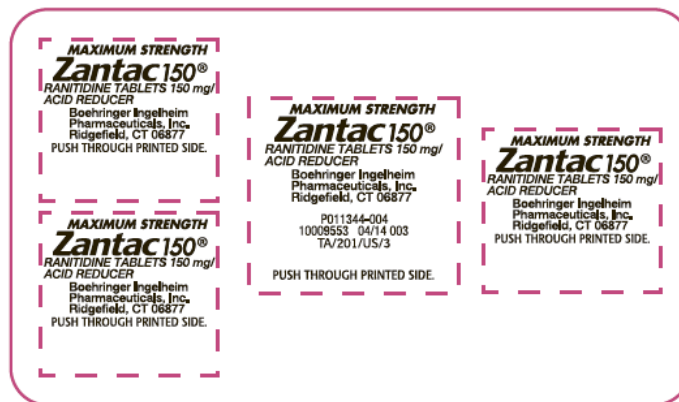
ALL SMALL TEXT - 4.4 PT HELVETICA NEUE CONDENSED

HORIZONTAL SCALE 80%

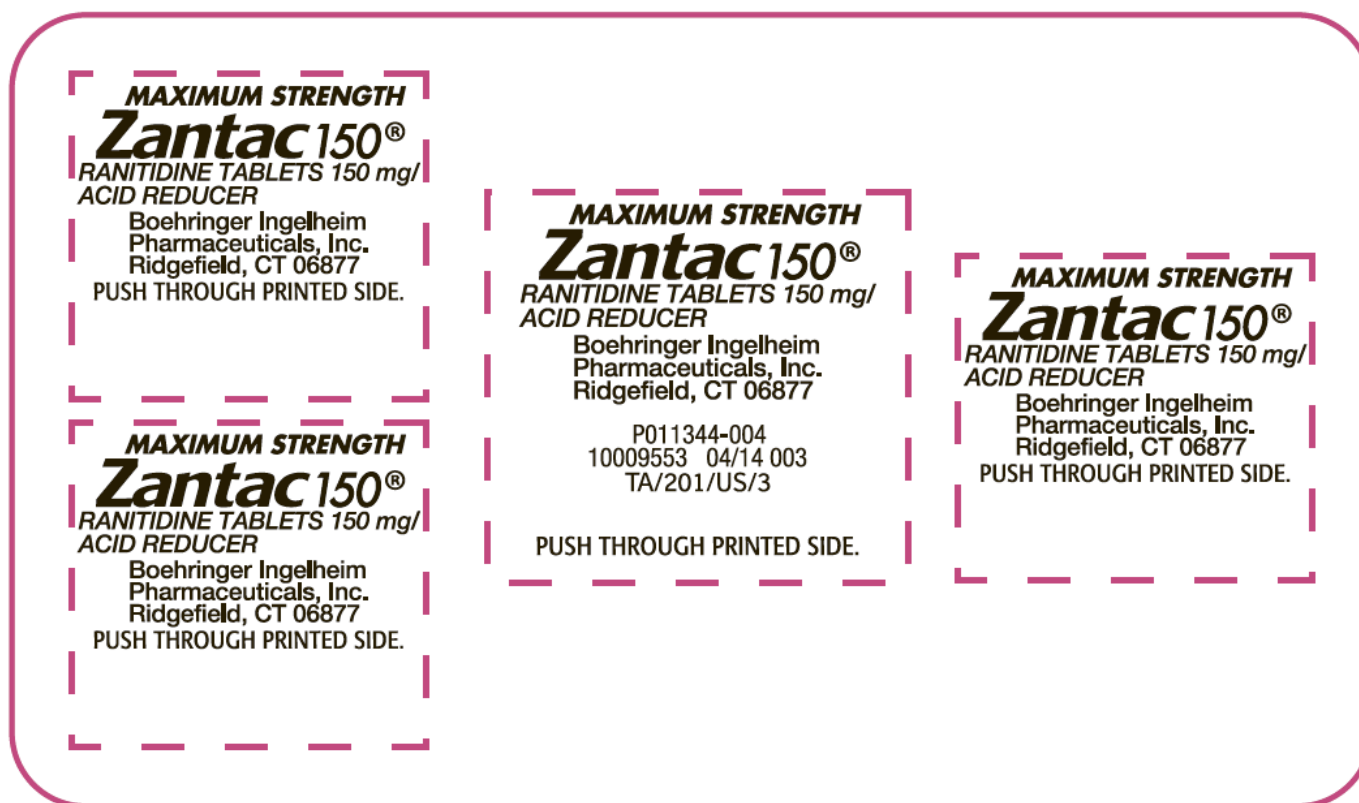
BULLETS - 4.5 PT

MM ■


| |
|---|
|  Boehringer Ingelheim |
| Copy for NDA Submission |
| Product: Zantac 150[®] |
| Component: 150 mg 3ct Blister Foil Label |
| Date: July 2014 |



100%



200%

| |
|---|
|  Boehringer Ingelheim |
| Copy for NDA Submission |
| Product: Zantac 150[®] |
| Component: 150 mg 8ct Blister Foil Label |
| Date: July 2014 |



100%



200%

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 150®

Component:
150 mg 8ct Blister Carton

Date:
February 2015

MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150mg/Acid Reducer
150

MAXIMUM STRENGTH
Zantac
Ranitidine Tablets 150 mg/Acid Reducer
150

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

8 TABLETS (8 DOSES)

Drug Facts

Active ingredient (in each tablet)
 Ranitidine 150 mg (as ranitidine hydrochloride 168 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
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.
Do not use if you are allergic to ranitidine or other acid reducers

Warnings
 • frequent chest pain • frequent wheezing, particularly with heartburn • unexplained weight loss
 • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
 • stomach pain
 • your heartburn continues or worsens • you need to take this product for more than 14 days

Stop use and ask a doctor if
 • you have kidney disease, except under the advice and supervision of a doctor
 • you have acid reflux
 • 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.

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
 • frequent chest pain • frequent wheezing, particularly with heartburn • unexplained weight loss
 • stomach pain
 • your heartburn continues or worsens • you need to take this product for more than 14 days

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
 • 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
 • store at 20°-25°C (68°-77°F)
 • avoid excessive heat or humidity
 • this product is sodium and sugar free

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

Drug Facts (continued)
 M-F, 8:30-5 EST, or visit www.zantac.com
 Questions? call 1-888-285-9159 (English/Spanish)
 Copyright © 2015, Boehringer Ingelheim Pharmaceuticals, Inc. All rights reserved.
 Products U.S. version of Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877
 Product of Spain. Manufactured in Mexico.

LOT
EXP

8 81421 03102 8

ZANTAC does not supply store brands

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 24ct Blister Carton

Date:
February 2015

LOT

EXP

Drug Facts (continued)

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

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

Boehringer Ingelheim Consumer Health Care
Product: Based on the information provided by the manufacturer.
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877
Product of Spain. Manufactured in Mexico.

MAXIMUM STRENGTH Zantac 150
Ranitidine Tablets 150 mg/Acid Reducer

Drug Facts

Active ingredient (in each tablet)
Ranitidine 150 mg (as ranitidine hydrochloride 188 mg) Acid reducer

Uses
• relieves heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages
• prevents heartburn associated with acid indigestion and sour stomach

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
• 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 difficulty swallowing, 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
• 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

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 prevent symptoms, swallow 1 tablet with a glass of water
• to relieve symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages
• can be used up to twice daily (do not take more than 2 tablets in 24 hours)

Other information
• do not use if individual blister unit 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
titanium dioxide, triacetin, hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide.

090320955/4
P011079-006
CT8130A
2/15 004

MAXIMUM STRENGTH Zantac 150
Ranitidine Tablets 150 mg/Acid Reducer

MAXIMUM STRENGTH Zantac 150
Ranitidine Tablets 150 mg/Acid Reducer

517

MAXIMUM STRENGTH Zantac 150
Ranitidine Tablets 150 mg/Acid Reducer


6 81421 03103 5

ZANTAC does not supply store brands

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 50ct 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 • 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 • heartburn with **lightheadedness, sweating or dizziness** • chest pain or neck or shoulder pain • unexplained weight loss • nausea or vomiting, particularly with heartburn • unexplained weight loss • heartburn worsens or 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 **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. 10009606 4/14 002 P030536-003

LOT
EXP

090330976/2

364

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 • 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 • heartburn with **lightheadedness, sweating or dizziness** • chest pain or neck or shoulder pain • unexplained weight loss • nausea or vomiting, particularly with heartburn • unexplained weight loss • heartburn worsens or 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 **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. 10009606 4/14 002 P030536-003


LOT
EXP

090330976/2

364

200%

FDA NARRATIVE FORMAT COPY
NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
HEADINGS- 5 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 5 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT - 5 PT HELVETICA NEUE CONDENSED
HORIZONTAL SCALE 75%
BULLETS - 5 PT
MM ■

 **Boehringer Ingelheim**

Copy for NDA Submission

Product:
Zantac 150®

Component:
150 mg 50ct Bottle Carton

Date:
February 2015

090320956/5
P011081-007
CT6134A
2/15 004

50 TABLETS (50 DOSES)

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach



Zantac 150
MAXIMUM STRENGTH
Ranitidine Tablets 150 mg/Acid Reducer

518



50 TABLETS (50 DOSES)

Zantac 150
MAXIMUM STRENGTH
Ranitidine Tablets 150 mg/Acid Reducer



6 81421 03104 2

Drug Facts

| | |
|---|--------------------------------|
| Active ingredient (in each tablet) Ranitidine 150 mg (as ranitidine hydrochloride 168 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
- 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 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

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

Zantac 150
MAXIMUM STRENGTH
Ranitidine Tablets 150 mg/Acid Reducer

50 TABLETS (50 DOSES)

LOT
EXP

ZANTAC does not supply store brands

Drug Facts (continued)

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
Division of **Boehringer Ingelheim Pharmaceuticals, Inc.**, Ridgefield, CT 06877
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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 65ct Bottle Label |
| Date: July 2014 |




100%



200%

FDA NARRATIVE FORMAT COPY
NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
HEADINGS- 5 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS- 5 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT - 5 PT HELVETICA NEUE CONDENSED
HORIZONTAL SCALE 75%
BULLETS - 5 PT
MM ■

 **Boehringer
Ingelheim**

**Copy for NDA
Submission**

Product:
Zantac 150®

Component:
**150 mg 65ct
Bottle Carton**

Date:
February 2015

0903209677
P010780-010
CT6136A
2/15 004

65 TABLETS (65 DOSES)

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



Zantac 150
MAXIMUM STRENGTH
Ranitidine Tablets 150 mg/Acid Reducer

519



65 TABLETS (65 DOSES)

Zantac 150
MAXIMUM STRENGTH
Ranitidine Tablets 150 mg/Acid Reducer



6 81421 03105 9

Drug Facts

| Active ingredient (in each tablet) | Purpose |
|--|--------------|
| Ranitidine 150 mg (as ranitidine hydrochloride 168 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
- 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.
- 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
- nausea or vomiting
- stomach pain
- heartburn with lightheadedness, sweating or dizziness
- lightheadedness
- unexplained weight loss

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
- avoid excessive heat or humidity
- store at 20°-25°C (68°-77°F)
- this product is sodium and sugar free

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

**MAXIMUM STRENGTH
Zantac 150**
Ranitidine Tablets 150 mg/Acid Reducer

65 TABLETS (65 DOSES)

LOT
EXP

ZANTAC does not supply store brands

Drug Facts (continued)

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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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 80ct Pouch Dispenser

Date:
February 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)

| |
|---|
|  Boehringer Ingelheim |
| Copy for NDA Submission |
| Product: Zantac 150[®] |
| Component: 150 mg Consumer Leaflet |
| Date: July 2014 |



**What you should know about
MAXIMUM STRENGTH
Zantac[®]**
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?**

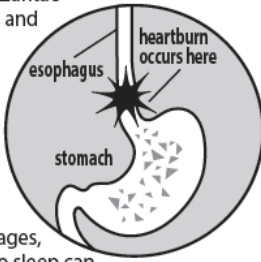
- MAXIMUM STRENGTH Zantac 150 contains 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

**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.

**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.



**How should I take
MAXIMUM STRENGTH
Zantac 150?**

- 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.
- 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

09034024/4

**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.

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P011213-004
10009711
4/14 004

09034024/4

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|  Boehringer Ingelheim |
| Copy for NDA Submission |
| Product: Zantac 150® Cool Mint |
| Component: 150 mg Cool Mint 8ct Blister Foil Label |
| Date: July 2014 |

| | | |
|--|---|--|
| COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE. | COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE. | COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE. |
| COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE. | COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE. P011082-005 10009590 TA/206/US/4 4/14 004 | COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE. |
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Boehringer Ingelheim

Copy for NDA Submission

Product:
**Zantac 150®
Cool Mint**

Component:
**150 mg Cool Mint 50ct
Bottle Label**

Date:
February 2015




100%



200%

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 HORIZONTAL SCALE 84%
 BULLETS - 4.75 PT
 MM ■

 **Boehringer Ingelheim**

Copy for NDA Submission

Product:
**Zantac 150®
 Cool Mint**

Component:
**150 mg Cool Mint 50ct
 Bottle Carton**

Date:
February 2015



50 TABLETS (50 DOSES)

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

RELEASING A COOLING SENSATION IN MOUTH & THROAT

Zantac 150
 Ranitidine Tablets 150 mg/Acid Reducer

MAXIMUM STRENGTH COOL MINT TABLETS

Zantac 150
 Ranitidine Tablets 150 mg/Acid Reducer

MAXIMUM STRENGTH COOL MINT TABLETS

090321649/3
 P030168-005
 CT8151A
 2/15 003

50 TABLETS (50 DOSES)

Zantac 150
 Ranitidine Tablets 150 mg/Acid Reducer

MAXIMUM STRENGTH COOL MINT TABLETS

50 TABLETS (50 DOSES)

Zantac 150
 Ranitidine Tablets 150 mg/Acid Reducer

MAXIMUM STRENGTH COOL MINT TABLETS

LOT
EXP

Drug Facts

| Active ingredient (in each tablet) | Purpose |
|---|--------------|
| Ranitidine 150 mg (as ranitidine hydrochloride 168 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
- 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 health professional before use.

Drug Facts (continued)

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 (up to 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
- 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 No.1, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate, sucralose, titanium dioxide

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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 Division of Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877
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ZANTAC does not supply store brands

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 150®
Cool Mint**

Component:
**150 mg Cool Mint 65ct
Bottle Label**

Date:
February 2015

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 • 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 • 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 worsens or 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.**

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

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 1-888-285-9169 (English/Spanish) M-F, 8:30-5 EST, or visit www.zantacotc.com Copyright © 2015, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. All rights reserved. L6154A 2/15 001 P035462-001

LOT

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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 • 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 • 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 worsens or 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.**

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

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 1-888-285-9169 (English/Spanish) M-F, 8:30-5 EST, or visit www.zantacotc.com Copyright © 2015, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. All rights reserved. L6154A 2/15 001 P035462-001

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NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
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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 150®
Cool Mint Tablets**

Component:
**150 mg Cool Mint 65ct
Bottle Carton**

Date:
February 2015

65 TABLETS (65 DOSES)

RELEASING A COOLING SENSATION IN MOUTH & THROAT

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

Zantac 150
Ranitidine Tablets 150 mg/Acid Reducer

COOL MINT TABLETS
MAXIMUM STRENGTH

COOL MINT TABLETS
MAXIMUM STRENGTH
Zantac 150
Ranitidine Tablets 150 mg/Acid Reducer

090321650/3
P030171-005
CT6153A
2/15 003

COOL MINT TABLETS
MAXIMUM STRENGTH
Zantac 150
Ranitidine Tablets 150 mg/Acid Reducer

65 TABLETS (65 DOSES)

Drug Facts
Active ingredient (in each tablet) Purpose
Ranitidine 150 mg (as ranitidine hydrochloride 168 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
• 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 health professional before use.

Drug Facts (continued)
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 (up to 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
• 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 No. 1, flavors, hydroxyethylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate, sucralose, titanium dioxide

Questions? call 1-888-285-9159 (English/Spanish) M-F, 8:30 - 5 EST, or visit www.zantac150.com

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

LOT
EXP

ZANTAC does not supply store brands

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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 150® Cool Mint |
| Component: 150 mg Cool Mint Consumer Leaflet |
| Date: July 2014 |

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What you should know about

COOL MINT TABLETS

MAXIMUM STRENGTH

Zantac

RANITIDINE TABLETS 150 mg **150**[®]
ACID REDUCER

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

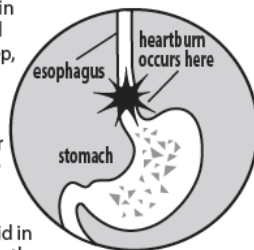
What are MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets?

Excellent Safety Record

What symptoms does MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets relieve and prevent?

How should I take MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets?

- MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets contain 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.
- When swallowed, MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets release a cooling sensation in the mouth and throat.
- The ingredient in MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets has been taken safely with many frequently prescribed medications.
- MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets are sodium and sugar free.
- MAXIMUM STRENGTH Zantac 150 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.
- 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 (up to 2 tablets in 24 hours).
- Do not chew tablet. MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets should not be given to children under 12 years old unless directed by a doctor.



090340618/2

How do MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets work?

Tips for managing heartburn

When should I see a doctor?

- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers

MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets reduce the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets 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

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 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 1-888-285-9159 (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.

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Ridgefield, CT 06877
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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THERESA M MICHELE
03/12/2015