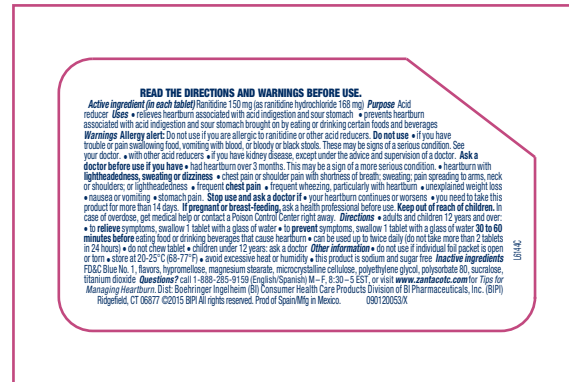
 Boehringer Ingelheim
Copy for NDA Submission
Product: Zantac 150® Cool Mint
Component: 150 mg Cool Mint 1ct Foil Packet
Date: November 2015

100%

FRONT

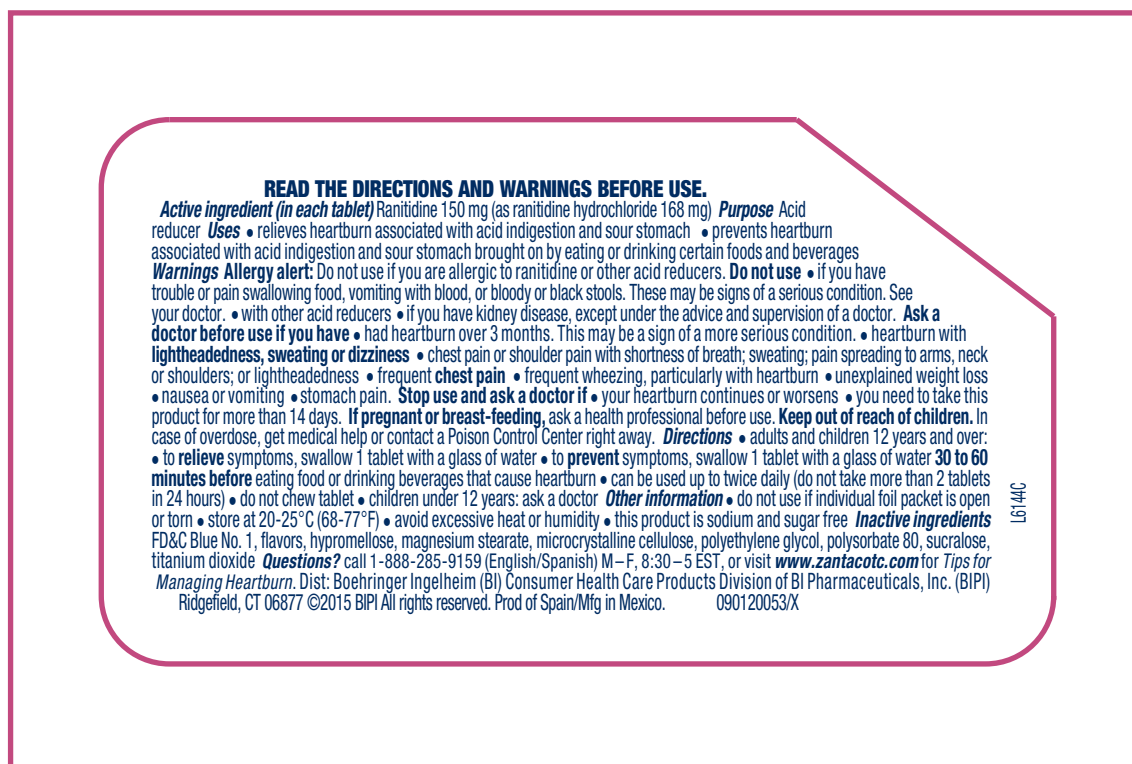
BACK



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® Cool Mint
Component: 150 mg Cool Mint 3ct Foil Packet Carton
Date: September 2015

LOT
ZANTAC does not supply store brands | EXP

www.zantacotc.com

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

Inactive ingredients: FD&C Blue No. 1, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyorbate 80, sucralose, titanium dioxide

Other information:

- store at 20-25°C (68-77°F)
- avoid excessive heat or humidity
- this product is sodium and sugar free
- do not use if individual foil packet 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
 - to 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)
 - do not chew tablet
 - Beverages that cause heartburn
- children under 12 years: ask a doctor

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

6 81421 03232 2

5 0

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

Zantac 150
Ranitidine Tablets 150 mg/Acid Reducer

COOL MINT TABLETS

MAXIMUM STRENGTH

Zantac

Ranitidine Tablets 150 mg/Acid Reducer **150**

**ON-THE-GO
PACKS**

**3 Portable
Packs**

**1 Tablet
per Pack**



PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

SUGAR FREE **3 TABLETS (3 DOSES)**



03232 81421 6

5 0

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03232 81421 6

Drug Facts

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;
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders;
- 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.

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 – 84%

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 8ct Blister Carton
Date: September 2015

Boehringer Ingelheim

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ZANTAC does not supply store brands

6 81421 03201 8

CT6148B
9/15

269

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

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.

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

Stop use and ask a doctor if
your heartburn continues or worsens
more than 14 days
before use.

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

LOT
EXP

Zantac 150[®]
Ranitidine Tablets 150 mg/Acid Reducer

COOL MINT TABLETS
MAXIMUM STRENGTH

Zantac

Ranitidine Tablets 150 mg/Acid Reducer 150[®]

Releases a
Cooling Sensation
in Mouth &
Throat


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

SUGAR FREE **8 TABLETS (8 DOSES)** 

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 8ct Blister Foil
Date: May 2015

COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.
COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE. BL6147A 5/15	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.
COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.

100%

COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.
COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE. BL6147A 5/15	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.
COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.	COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150® RANITIDINE TABLETS 150 mg/ ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 PUSH THROUGH PRINTED SIDE.

200%

 Boehringer Ingelheim
Copy for NDA Submission
Product: Zantac 150® Cool Mint
Component: 150 mg Cool Mint 32ct Blister Carton
Date: September 2015

LOT
EXP

Zantac
MAXIMUM STRENGTH
Cool Mint Tablets 150 mg / Acid Reducer

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

BONUS! 8 FREE TABLETS
BONUS! 8 FREE TABLETS

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

**Releases a
Cooling Sensation
in Mouth &
Throat**

**SUGAR
FREE**

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

32 TABLETS
(32 DOSES)

Z

CT6150B
9/15

274

Drug Facts
Ranitidine 150 mg
(as ranitidine hydrochloride 168 mg) Acid reducer

Active ingredient (in each tablet) Purpose

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, except under the advice and supervision of a doctor
if you have kidney disease, except under the advice and supervision of a doctor

Ask a doctor before use if you have
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 heartburn, particularly with heartburn
unexplained weight loss
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)
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 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 P&C Blue No. 1, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, titanium dioxide

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

Read the directions, and warnings before use.
Keep the carton, it contains important information.

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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 50ct
Bottle Carton**

Date:
September 2015

Zantac
MAXIMUM STRENGTH
COOL MINT TABLETS

Ranitidine Tablets 150 mg/Acid Reducer
150

CT6151B
9/15

Zantac
MAXIMUM STRENGTH
COOL MINT TABLETS

Ranitidine Tablets 150 mg/Acid Reducer
150

CT6151B
9/15

278

Zantac
MAXIMUM STRENGTH
COOL MINT TABLETS

Ranitidine Tablets 150 mg/Acid Reducer
150

50 TABLETS
(50 DOSES)

6 81421 03203 2

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 (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
- 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 80, 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.**

LOT
EXP

ZANTAC does not supply store brands

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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)

 <p>Boehringer Ingelheim</p>
<p>Copy for NDA Submission</p>
<p>Product: Zantac 150® Cool Mint</p>
<p>Component: 150 mg Cool Mint 50ct Bottle Label</p>
<p>Date: September 2015</p>




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 ■

 <p>Boehringer Ingelheim</p>
<p>Copy for NDA Submission</p>
<p>Product: Zantac 150® Cool Mint</p>
<p>Component: 150 mg Cool Mint 65ct Bottle Label</p>
<p>Date: September 2015</p>




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 150® Cool Mint Tablets
Component: 150 mg Cool Mint 75ct Bottle Carton
Date: September 2015



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



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

BONUS! 10 FREE ON-THE-GO PACKS INSIDE!

BONUS! 10 FREE ON-THE-GO PACKS INSIDE!

CT6575B
9/15

75 TABLETS (75 DOSES)



6 81421 03231 5

75 TABLETS (75 DOSES)

LOT
EXP

ZANTAC does not supply store brands

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Ranitidine 150 mg Acid reducer (as ranitidine hydrochloride 168 mg)</p> <p>Uses</p> <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 <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers.</p> <p>Do not use</p> <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 if you have kidney disease, except under the advice and supervision of a doctor <p>Ask a doctor before use if you have</p> <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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> your heartburn continues or worsens you need to take this product for more than 14 days <p>If pregnant or breast-feeding, ask a health professional before use.</p>	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <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) do not chew tablet children under 12 years: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> do not use if printed foil under bottle cap is open or torn 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 <p>Inactive ingredients FD&C Blue No. 1, flavors, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, sucralose, titanium dioxide</p> <p>Questions? call 1-888-285-9159 (English/Spanish) M-F, 8:30-5 EST, or visit www.zantacotc.com</p> <p style="text-align: center;">Read the directions, consumer information leaflet and warnings before use. Keep the carton. It contains important information.</p>
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282

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 78ct Bottle Carton
Date: September 2015



Zantac
MAXIMUM STRENGTH
COOL MINT TABLETS

150
Ranitidine Tablets 150 mg/Acid Reducer

78 TABLETS (78 DOSES)

CT6155B
9/15

**Releases a
Cooling Sensation
in Mouth &
Throat**

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

78 TABLETS (78 DOSES)

**SUGAR
FREE**



4 5 6

BONUS! 13 FREE TABLETS

BONUS! 13 FREE TABLETS



Zantac
MAXIMUM STRENGTH
COOL MINT TABLETS

150
Ranitidine Tablets 150 mg/Acid Reducer

78 TABLETS (78 DOSES)

CT6155B
9/15

Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Ranitidine 150 mg (as ranitidine hydrochloride 168 mg) Acid reducer		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.			
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 • 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 80, 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.			



Zantac
MAXIMUM STRENGTH
COOL MINT TABLETS

150
Ranitidine Tablets 150 mg/Acid Reducer

78 TABLETS (78 DOSES)

LOT
EXP

ZANTAC does not supply store brands

6 81421 03204 9

Boehringer Ingelheim

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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 78ct Bottle Label
Date: September 2015




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® Cool Mint
Component: 150 mg Cool Mint 90ct Bottle Carton
Date: September 2015



Zantac 150
MAXIMUM STRENGTH
COOL MINT TABLETS

VALUE SIZE 90 TABLETS

Ranitidine Tablets 150 mg/Acid Reducer

90 TABLETS (90 DOSES)

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

Releases a Cooling Sensation in Mouth & Throat™

FREE SUGAR

CT6219A
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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 (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
• 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 80, 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.

LOT
EXP

ZANTAC does not supply store brands.

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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 90ct 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 150® Cool Mint

Component:
150 mg Cool Mint Consumer Leaflet

Date:
September 2015

Boehringer Ingelheim

What you should know about COOL MINT TABLETS MAXIMUM STRENGTH Zantac 150®
Ranitidine Tablets 150 mg/ 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?

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

• 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.

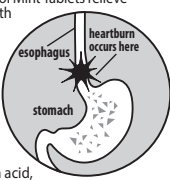
• To **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn.

This medicine can be used up to twice daily (do not take more than 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.

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



MANUFACTURER'S COUPON OFFER EXPIRES 12/31/2018

Save \$100 on any Zantac® product 24ct or larger



How do MAXIMUM STRENGTH Zantac 150 Cool Mint Tablets work?

Tips for managing heartburn

When should I see a doctor?

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.
- 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.

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


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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/

DANIEL BRUM

11/20/2015

Signed on behalf of Karen M. Mahoney