

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75[®] Cool Mint

Component:
75 mg Cool Mint 1ct Foil Packet

Date:
December 2015

100%

FRONT

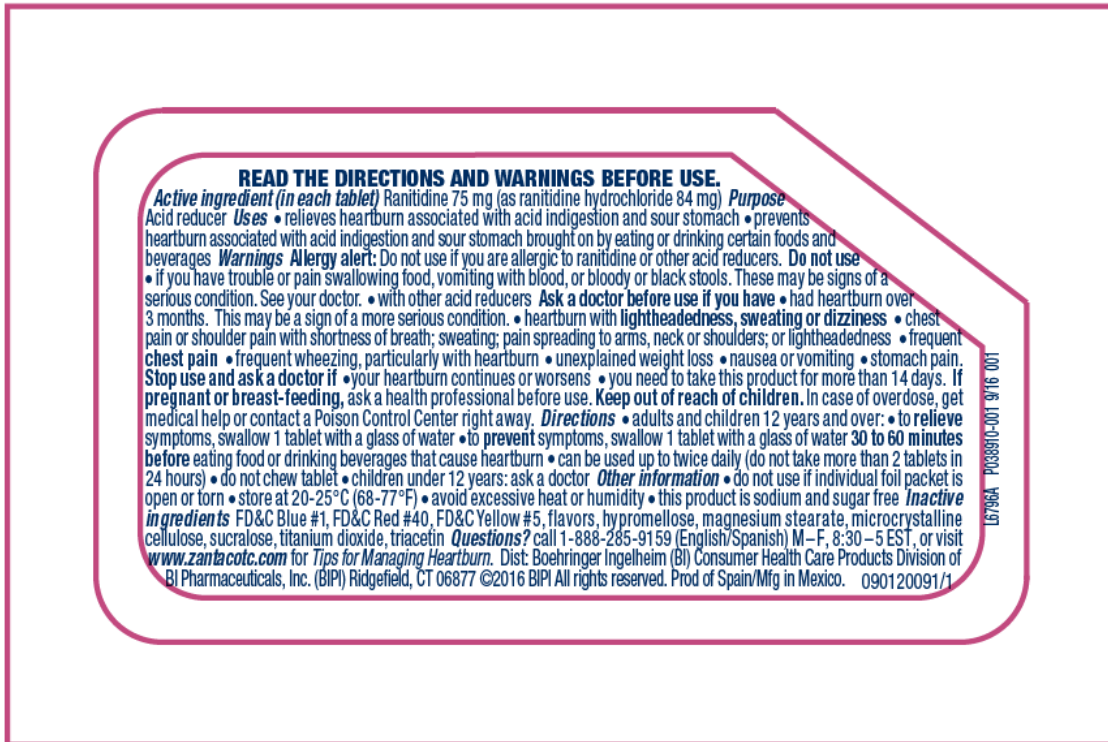
BACK



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 75® Cool Mint
Component: 75 mg Cool Mint 10ct Blister Foil
Date: July 2015

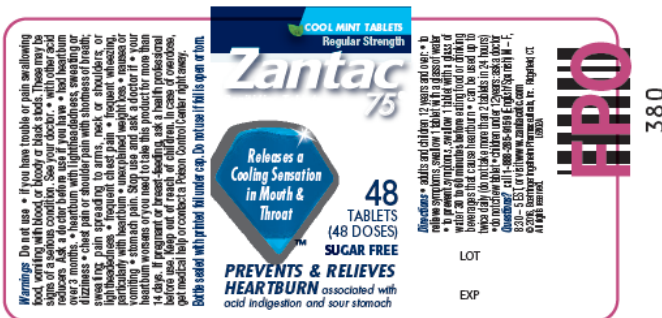


100%



200%

 <p>Boehringer Ingelheim</p>
<p>Copy for NDA Submission</p>
<p>Product: Zantac 75[®] Cool Mint</p>
<p>Component: 75 mg Cool Mint 48ct 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 75[®] Cool Mint
Component:	75 mg Cool Mint 48ct Bottle Carton
Date:	September 2015

CT6801A
9/15 001

NEW

COOL MINT TABLETS

Zantac
Regular Strength

Ranitidine Tablets 75 mg/Acid Reducer

75

FPO

508

48 TABLETS (48 DOSES)

SUGAR FREE

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

Releases a Cooling Sensation in Mouth & Throat

COOL MINT TABLETS

Zantac
Regular Strength

75

Ranitidine Tablets 75 mg/Acid Reducer

48 TABLETS (48 DOSES)

Drug Facts

Active ingredient (in each tablet) Ranitidine 75 mg (as ranitidine hydrochloride 84 mg)	Purpose Acid reducer
---	--------------------------------

Uses

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

Warnings

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

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain • 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
- store at 20-25°C (68-77°F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

COOL MINT TABLETS

Zantac
Regular Strength

75

Ranitidine Tablets 75 mg/Acid Reducer

48 TABLETS (48 DOSES)

LOT
EXP

ZANTAC does not supply store brands

COOL MINT TABLETS

Zantac
Regular Strength

75

Ranitidine Tablets 75 mg/Acid Reducer

48 TABLETS (48 DOSES)

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.zantacolc.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
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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

COOL MINT TABLETS
Regular Strength

Zantac 75

Releases a Cooling Sensation in Mouth & Throat

60 TABLETS (60 DOSES)
SUGAR FREE

PREVENTS & RELIEVES 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 • 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.**

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

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

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LOT
EXP

380

100%

COOL MINT TABLETS
Regular Strength

Zantac 75

Releases a Cooling Sensation in Mouth & Throat

60 TABLETS (60 DOSES)
SUGAR FREE

PREVENTS & RELIEVES 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 • 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.**

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LOT
EXP

380

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

CT6803A
9/15 001

Zantac 75[®]
Ranitidine Tablets 75 mg/Acid Reducer
Regular Strength
COOL MINT TABLETS

60 TABLETS (60 DOSES)

FPO

6 81421 03006 9

Zantac 75[®]
Ranitidine Tablets 75 mg/Acid Reducer
Regular Strength
COOL MINT TABLETS

NEW

Zantac 75[®]
Ranitidine Tablets 75 mg/Acid Reducer
Regular Strength
COOL MINT TABLETS

Drug Facts

Active ingredient (in each tablet) Ranitidine 75 mg (as ranitidine hydrochloride 84 mg)	Purpose Acid reducer
Uses	
<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 	
Warnings	
<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 <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>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
Directions	
<p>adults and children 12 years and over:</p> <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 <p>can be used up to twice daily (do not take more than 2 tablets in 24 hours)</p> <ul style="list-style-type: none"> do not chew tablet <p>children under 12 years: ask a doctor</p>	
Other information	
<ul style="list-style-type: none"> do not use if printed foil under bottle cap is open or torn avoid excessive heat or humidity 	<ul style="list-style-type: none"> 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.zantac75.com

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

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Zantac 75[®]
Ranitidine Tablets 75 mg/Acid Reducer
Regular Strength
COOL MINT TABLETS

60 TABLETS (60 DOSES)

FPO

LOT
EXP

ZANTAC does not supply store brands

FPO

508

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 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

CT6805A
915 001

Zantac
Regular Strength
Cool Mint TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
75

NEW

BONUS! 12 FREE TABLETS

BONUS! 12 FREE TABLETS

Zantac
Regular Strength
Cool Mint TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
75

FPO

55

Zantac
Regular Strength
Cool Mint TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
72 (72 DOSES)

FPO

6 81421 03007 6

Drug Facts

Active ingredient (in each tablet)
Ranitidine 75 mg (as ranitidine hydrochloride 84 mg).....**Purpose**
Acid reducer

Uses

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

Warnings

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

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent chest pain • 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 • store at 20-25°C (68-77°F)
- avoid excessive heat or humidity • this product is sodium and sugar free

Zantac
Regular Strength
Cool Mint TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
72 (72 DOSES)

FPO

LOT
EXP

ZANTAC does not supply slave brands

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.

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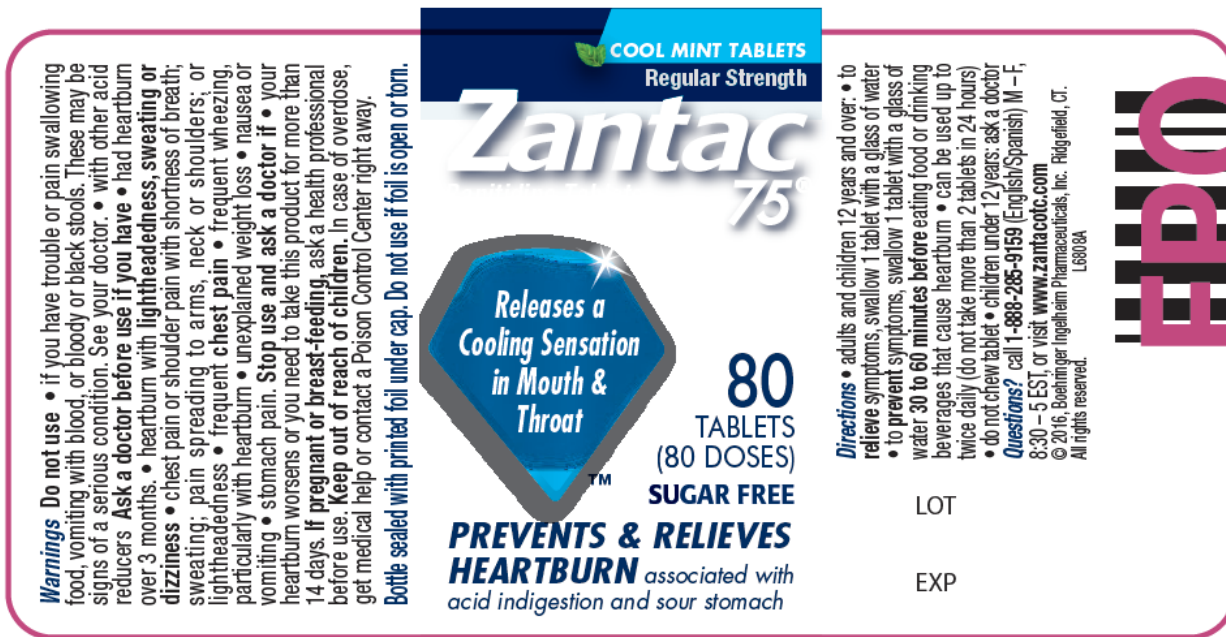
STANDARD FORMAT/ HELVETICA NEUE 100% SCALE

- 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 75[®] Cool Mint</p>
<p>Component: 75 mg Cool Mint 80ct 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 75[®]
Cool Mint**

Component:
**75 mg Cool Mint
80ct Bottle Carton**

Date:
September 2015

CT7807A
9/15 001

NEW

COOL MINT TABLETS

Zantac
Regular Strength
Ranitidine Tablets 75 mg/Acid Reducer

75

**80 TABLETS
(80 DOSES)**

SUGAR FREE

Releases a Cooling Sensation in Mouth & Throat

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

COOL MINT TABLETS

Zantac
Regular Strength
Ranitidine Tablets 75 mg/Acid Reducer

**80 TABLETS
(80 DOSES)**

6 81421 03007 6

FPO

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

COOL MINT TABLETS

Zantac
Regular Strength
Ranitidine Tablets 75 mg/Acid Reducer

**80 TABLETS
(80 DOSES)**

FPO

LOT
EXP

ZANTAC does not supply store brands

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.

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- HEAVY RULE - 2.5 PT
- LIGHT RULE -.5 PT
- HORIZONTAL SCALE 85%
- BULLETS - 5 PT
- MM ■ 3/64" -Gap (Border -type)

 <p>Boehringer Ingelheim</p>
<p>Copy for NDA Submission</p>
<p>Product: Zantac 75® Cool Mint</p>
<p>Component: 75 mg Cool Mint 96ct 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
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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

CT6809A
915 001

Zantac
Regular Strength
Cool Mint TABLETS

BONUS! 16 FREE TABLETS

BONUS! 16 FREE TABLETS

Zantac
Regular Strength
Cool Mint TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
75

FPO

55

Zantac
Regular Strength
Cool Mint TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
96 TABLETS (96 DOSES)

FPO

6 81421 03007 6

Drug Facts

Active ingredient (in each tablet)
Ranitidine 75 mg (as ranitidine hydrochloride 84 mg).....**Purpose**
Acid reducer

Uses

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

Warnings

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

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
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- frequent chest pain • frequent wheezing, particularly with heartburn • unexplained weight loss
- nausea or vomiting • stomach pain

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- children under 12 years: ask a doctor

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- 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

Zantac
Regular Strength
Cool Mint TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
96 TABLETS (96 DOSES)

FPO

LOT
EXP

ZANTAC does not supply slave brands

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


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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 75® Cool Mint
Component: 75 mg Cool Mint Consumer Leaflet
Date: July 2015

**What you should know about
COOL MINT TABLETS**
Zantac
Ranitidine Tablets 75 mg/
Acid Reducer **75®**

(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?**

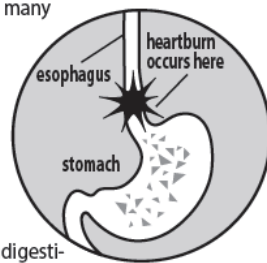
- Zantac 75 Cool Mint Tablets contain 75 mg of ranitidine (as ranitidine hydrochloride, 84 mg), a medicine that doctors have prescribed more than 200 million times worldwide.

**Excellent Safety
Record**

- When swallowed, Zantac 75 Cool Mint Tablets release a cooling sensation in the mouth and throat.
- 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.

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

- Zantac 75 Cool Mint Tablets are sodium and sugar free.
- 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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