

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®

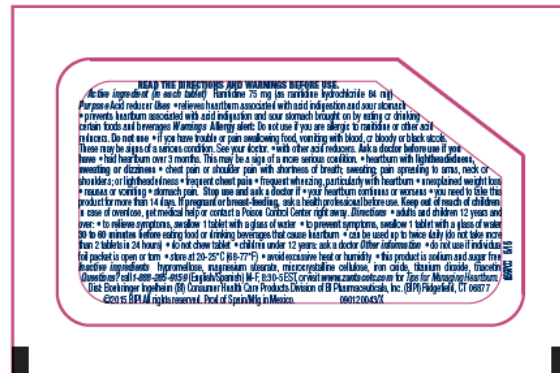
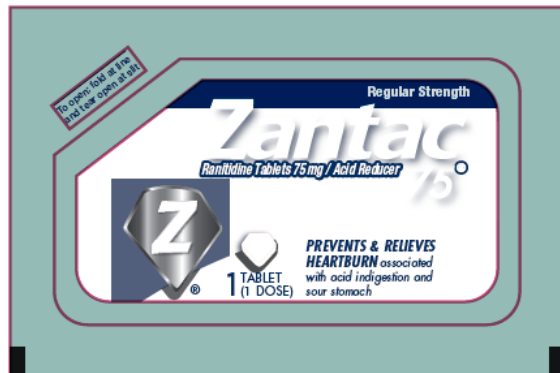
Component:
**75 mg 1ct
Foil Packet**

Date:
November 2015

100%

FRONT

BACK



200%



FRONT



BACK

FDA NARRATIVE FORMAT COPY

NARRATIVE FORMAT/ HELVETICA NEUE 90% SCALE

HEADINGS – 4.5 PT HELVETICA NEUE BOLD CONDENSED ITALIC

SUBHEADS- 4.5 PT HELVETICA NEUE BOLD CONDENSED

ALL SMALL TEXT – 4.5 PT HELVETICA NEUE CONDENSED

HORIZONTAL SCALE 82%

BULLETS – 4.5 PT

MM ■

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75[®]

Component:
75 mg 4ct Blister Carton

Date:
May 2015

Drug Facts (continued)

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

Drug Facts (continued)

Other information

- this product is sodium and sugar free
- avoid excessive heat or humidity
- store at 20-25°C (68-77°F)
- do not use if individual blister unit 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 or 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

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

Warnings

- 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

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

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

Purpose

Warnings

- 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

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

Warnings

- 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

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

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

Purpose

Warnings

- 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

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

Warnings

- 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

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

Regular Strength

Zantac
 Ranitidine Tablets 75 mg / Acid Reducer

75[®]

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

4 TABLETS (4 DOSES)

CTB118C
5/15

502

Regular Strength

Zantac
 Ranitidine Tablets 75 mg / Acid Reducer

75[®]

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

4 TABLETS (4 DOSES)

CTB118C
5/15

502

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 75[®]
Component: 75 mg 10ct Blister Foil Label
Date: May 2015

Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877
Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	BL6119A 5/15	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877
Push through printed side.			
Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877

100%

Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877
Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	BL6119A 5/15	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877
Push through printed side.			
Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877	Regular Strength Zantac 75[®] RANITIDINE TABLETS 75 mg ACID REDUCER Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877

200%

 **Boehringer
Ingelheim**

**Copy for NDA
Submission**

Product:
Zantac 75[®]

Component:
**75 mg 10ct
Blister Carton**

Date:
May 2015

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

Distributed by: Boehringer Ingelheim (B)
 Consumer Health Care Products
 Division of B Pharmaceutics, Inc., Ridgefield, CT 06877
 © 2015, B Pharmaceutics, Inc. All rights reserved.
 Product of Spain, Manufactured in Mexico.

Drug Facts

Active ingredient (in each tablet)
 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
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 • stomach pain
 • nausea or vomiting

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 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**
 • do not chew tablet

• children under 12 years: ask a doctor

• 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)
 • this product is sodium and sugar free
 • avoid excessive heat or humidity

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

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

ZANTAC does not supply store brands

81421 03003 8

Regular Strength
Zantac
 Ranitidine Tablets 75 mg / Acid Reducer

Regular Strength
Zantac
 Ranitidine Tablets 75 mg / Acid Reducer

75

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

10 TABLETS
(10 DOSES)

503

LOT
EXP

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 75®

Component:
75 mg 40ct Blister Carton

Date:
May 2015

LOT

EXP

Drug Facts (continued)

(Questions? call 1-888-285-0159 (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.

Distributed by: **Boehringer Ingelheim (B)**
Consumer Health Care Products
Division of B1 Pharmaceuticals, Inc.
Ridgefield, CT 06877
© 2015, B1 Pharmaceuticals, Inc.
All rights reserved.
Product of Spain. Manufactured in Mexico.
Boehringer Ingelheim

Drug Facts

Active ingredient (in each tablet)
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
• 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

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.
• 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

Stop use and ask a doctor if
• your heartburn continues or worsens • you need to take this product for more than 14 days
• 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 prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages
• to relieve heartburn, 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
• children under 12 years: ask a doctor

Other information
• do not use if individual tablet unit is open or torn
• store at 20-25°C (68-77°F)
• this product is sodium and sugar free
• avoid excessive heat or humidity

Inactive ingredients
titanium dioxide, thickeners, hypromellose, magnesium stearate, microcrystalline cellulose, iron oxide

CT61228
5/15

ZANTAC does not supply store brands

6 81421 03009 0

Regular Strength

Zantac
Ranitidine Tablets 75 mg / Acid Reducer

BONUS! 10 FREE TABLETS

BONUS! 10 FREE TABLETS

Regular Strength

Zantac
Ranitidine Tablets 75 mg / Acid Reducer

75

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

40 ~~30~~ TABLETS (40 DOSES)

Regular Strength

Zantac
Ranitidine Tablets 75 mg / Acid Reducer

507

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%

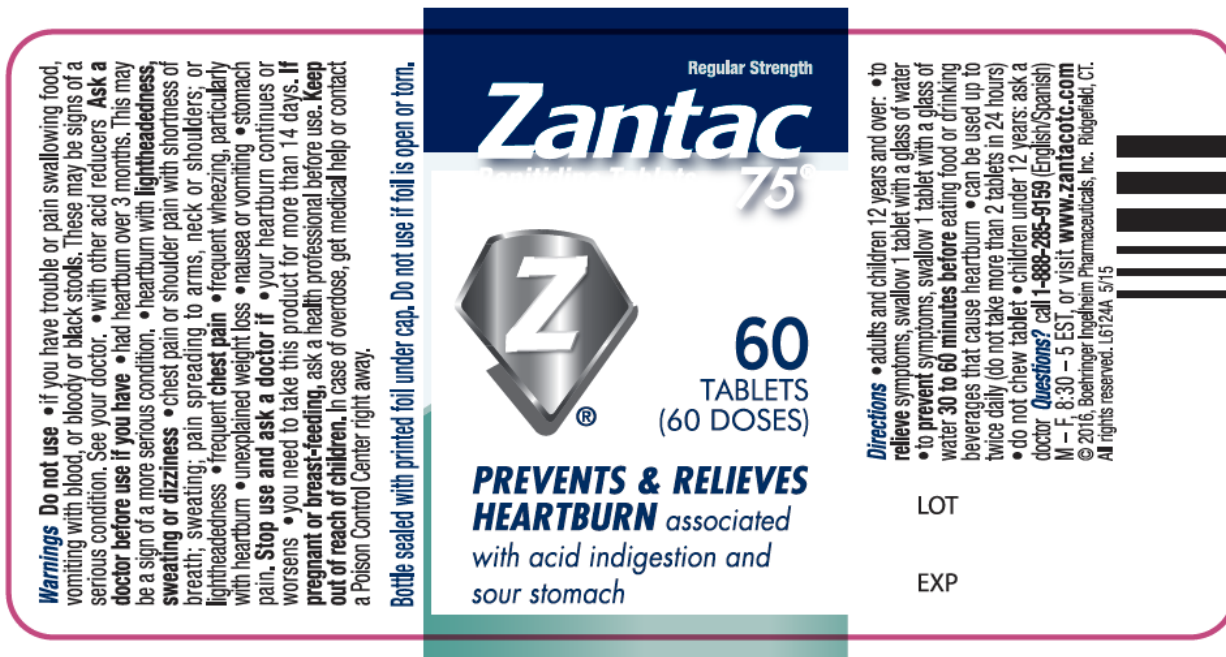
BULLETS – 5 PT

MM ■ 3/64" -Gap (Border -type)

 Boehringer Ingelheim
Copy for NDA Submission
Product: Zantac 75®
Component: 75 mg 60ct Bottle Label
Date: May 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 77%
BULLETS – 5 PT
MM ■

 **Boehringer
Ingelheim**

**Copy for NDA
Submission**

Product:
Zantac 75®

Component:
**75 mg 60ct
Bottle Carton**

Date:
May 2015

CT6123B
5/15

60 TABLETS (60 DOSES)

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



Zantac
Regular Strength

Ranitidine Tablets 75 mg / Acid Reducer

805



60 TABLETS (60 DOSES)

Zantac
Regular Strength

Ranitidine Tablets 75 mg / Acid Reducer



6 81421 03006 9

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

Ranitidine Tablets 75 mg / Acid Reducer

60 TABLETS (60 DOSES)

LOT
EXP

ZANTAC does not supply store brands.

Drug Facts (continued)

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

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


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

 Distributed by: **Boehringer Ingelheim (BI) Consumer Health Care Products**
Division of BI Pharmaceuticals, Inc., Ridgefield, CT 06877
© 2016, BI Pharmaceuticals, Inc. All rights reserved.
Product of Spain. Manufactured in Mexico.

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- 6/6.5 PT HELVETICA NEUE BOLD CONDENSED
- ALL SMALL TEXT – 6/6.5 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®
Component: 75 mg 80ct Bottle Label
Date: May 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 77%
BULLETS – 5 PT
MM ■

Boehringer Ingelheim

Copy for NDA Submission

Product:
Zantac 75®

Component:
75 mg 90ct Bottle Carton

Date:
May 2015

CT6482B
5/15

9080 TABLETS (90 DOSES)

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

10 FREE ON-THE-GO PACKS INSIDE 1 Tablet per Pack

75
Ranitidine Tablets 75 mg / Acid Reducer

Zantac
Regular Strength

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

Zantac
Regular Strength
Ranitidine Tablets 75 mg / Acid Reducer
75

FPO
175

Zantac
Regular Strength
Ranitidine Tablets 75 mg / Acid Reducer
90 TABLETS (90 DOSES)

6 81421 03022 9

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 • 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	

Zantac
Regular Strength
Ranitidine Tablets 75 mg / Acid Reducer
90 TABLETS (90 DOSES)

LOT
EXP

ZANTAC does not supply store brands

Drug Facts (continued)

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

Questions? call 1-888-285-0150 (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 Distributed by: **Boehringer Ingelheim (BI) Consumer Health Care Products**
Division of BI Pharmaceuticals, Inc., Ridgefield, CT 06877
© 2016, BI Pharmaceuticals, Inc. All rights reserved.
Product of Spain. Manufactured in Mexico.

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

DRUG FACTS – 9.1 PT HELVETICA NEUE BOLD CONDENSED ITALIC

DRUG FACTS (cont) – 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 75®
Component: 75 mg 96ct Bottle Label
Date: May 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 77%
BULLETS – 5 PT
MM ■

 **Boehringer
Ingelheim**

**Copy for NDA
Submission**

Product:
Zantac 75®

Component:
**75 mg 96ct
Bottle Carton**

Date:
May 2015

CT6127B
5/15



Zantac
Regular Strength
BONUS! 16 FREE TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
75

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

9680 TABLETS (96 DOSES)



175

CT6127B
5/15



Zantac
Regular Strength
BONUS! 16 FREE TABLETS

Ranitidine Tablets 75 mg/Acid Reducer
75



6 81421 03015 1

Zantac
Regular Strength
75

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

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	
Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers	
Do not use	
<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 	
Ask a doctor before use if you have	
<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 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • 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	
<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 	
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 • store at 20-25°C (68-77°F) • this product is sodium and sugar free 	

LOT
EXP

ZANTAC does not supply store brands

Drug Facts (continued)

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

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

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

 Distributed by: **Boehringer Ingelheim (BI)** Consumer Health Care Products
Division of **BI Pharmaceuticals, Inc.**, Ridgefield, CT 06877
© 2016, **BI Pharmaceuticals, Inc.** All rights reserved.
Product of Spain. Manufactured in Mexico.

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- 6/6.5 PT HELVETICA NEUE BOLD CONDENSED

ALL SMALL TEXT – 6/6.5 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®

Component:
75 mg Consumer Leaflet

Date:
September 2015

Boehringer Ingelheim

What you should know about Regular Strength Zantac 75®
Ranitidine Tablets 75 mg Acid Reducer

What is Zantac 75?
(Please read all of this information before taking Zantac 75. Save this leaflet for future reference.)
• Zantac 75 contains 75 mg of ranitidine (as ranitidine hydrochloride, 84 mg), a medicine that doctors have prescribed more than 200 million times worldwide.
• Zantac 75 has been used safely and effectively for years as an over-the-counter medication.

Excellent Safety Record

What symptoms does Zantac 75 relieve and prevent?


How should I take Zantac 75?

How does Zantac 75 work?

Additional tips for managing heartburn

MANUFACTURER'S COUPON OFFER EXPIRES 12/31/2018

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



Clinical studies prove Zantac 75 is effective in relieving... and preventing heartburn.

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

Percent of Heartburn Episodes Relieved

Study A

Group	% of Episodes
Zantac 75	57%
Placebo	38%

Study B

Group	% of Episodes
Zantac 75	50%
Placebo	38%

Percent of Patients with Prevention or Reduction of Heartburn Symptoms

Study C

Group	% of Patients
Zantac 75	69%
Placebo	45%

Study D

Group	% of Patients
Zantac 75	66%
Placebo	45%

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.zantac75.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.

Distributed by: **Boehringer Ingelheim (BI) Consumer Health Care Products**
Division of BI Pharmaceuticals, Inc., Ridgefield, CT 06877
© 2016, BI Pharmaceuticals, Inc. All rights reserved.

IT0534B 8/15

CONSUMER: LIMIT 1 COUPON PER PURCHASE of product indicated per transaction in same shopping trip. Coupons are not to be gathered and distributed by any person or group for charitable fund-raising purposes, authorized for purchasing products for resale, to be transferred, sold, auctioned, reproduced or altered from original. Any other use constitutes fraud. Coupons may not be redeemed for more than the purchase price of the product. Coupon may not be combined with other offers. Void where prohibited, taxed or otherwise restricted. Cash value 1/20¢. Do not send this coupon to **Boehringer Ingelheim Consumer Health Care Products Division**. **RETAILER:** We will reimburse the face value plus 8¢ handling if submitted in accordance with our Redemption Policy. For policy and/or coupon redemption, send to **Boehringer Ingelheim Consumer Health Care Products Division**, P.O. Box 880000, El Paso, TX 88588-0000. Improper use constitutes fraud. Copyright © 2016, **Boehringer Ingelheim Pharmaceuticals, Inc.** All rights reserved.

0681421-030597

