 **Boehringer  
Ingelheim**

**Copy for NDA  
Submission**

Product:  
**Zantac 150®**

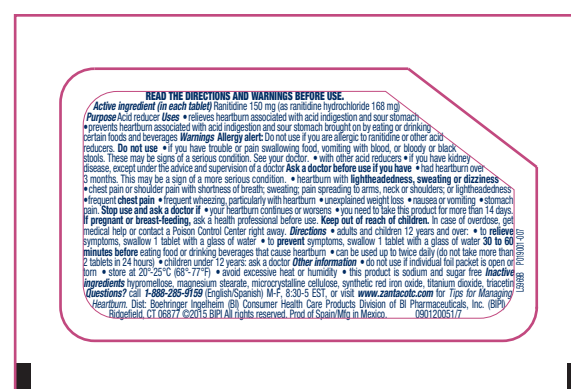
Component:  
**150 mg 1ct  
Foil Packet**

Date:  
**November 2015**

100%

FRONT

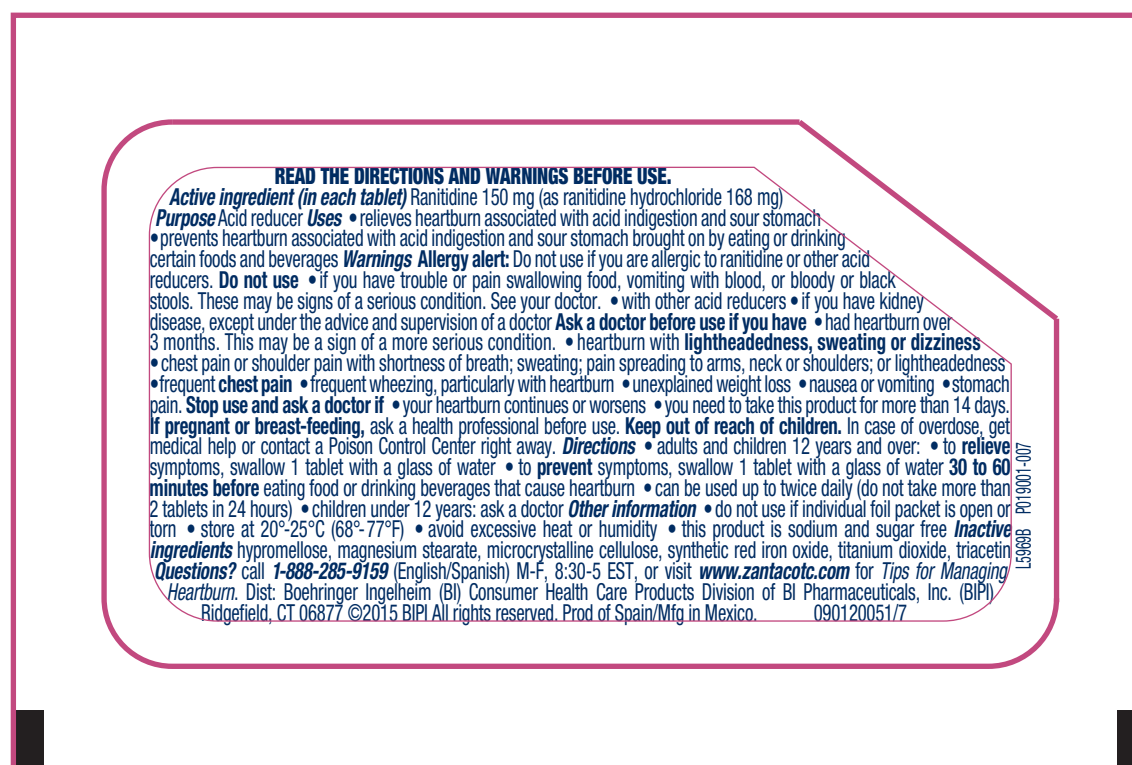
BACK



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
<b>Copy for NDA Submission</b>
Product: <b>Zantac 150®</b>
Component: <b>150 mg 3ct Foil Packet Carton</b>
Date: <b>September 2015</b>

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

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

FPO

ON-THE-GO  
PACKS

**3 Portable  
Packs**  
**1 Tablet  
per Pack**



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

**3 TABLETS**  
(3 DOSES)



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

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**Drug Facts**

**Active ingredient (in each tablet)**  
Ranitidine 150 mg (as ranitidine hydrochloride 168 mg).....acid reducer

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

PULL FLAP DOWN FOR CONTINUED DRUG FACTS ▼

**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)  
• children under 12 years: ask a doctor

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

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


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

LOT: \_\_\_\_\_ EXP: \_\_\_\_\_  
ZANTAC does not supply store brands

6 81421 03141 7  
XXXXXXXXXX  
81501

**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®**

Component:  
**150 mg 32ct  
Blister Carton**

Date:  
**September 2015**

LOT  
EXP

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

**Drug Facts (continued)**

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

Boehringer Ingelheim Consumer Health Care  
Pharmaceuticals, Inc., Ridgefield, CT 06877  
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**MAXIMUM STRENGTH  
Zantac  
150**  
Ranitidine Tablets 150 mg/Acid Reducer

6 81421 03117 2

090321348/4  
P022502-005  
CT6140A  
8/15 004

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

**BONUS! 8 FREE TABLETS  
BONUS! 8 FREE TABLETS**

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



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

**32** ~~24~~ TABLETS  
(32 DOSES)



301

**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)

 <b>Boehringer Ingelheim</b>
<b>Copy for NDA Submission</b>
Product: <b>Zantac 150<sup>®</sup></b>
Component: <b>150 mg 75ct Bottle Carton</b>
Date: <b>September 2015</b>



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

**75**

**Zantac**  
MAXIMUM STRENGTH

**BONUS! TO FREE ON-THE-GO PACKS INSIDE!**

**BONUS! TO FREE ON-THE-GO PACKS INSIDE!**

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

090XXXXXXXX/1  
PXXXXXX-001  
CT6514A  
8/15 001

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

**75 TABLETS  
(75 DOSES)**

6 81421 03140 0

**Drug Facts**

<b>Active ingredient (in each tablet)</b> Ranitidine 150 mg (as ranitidine hydrochloride 168 mg)	<b>Purpose</b> Acid reducer
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• relieves heartburn associated with acid indigestion and sour stomach</li> <li>• prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages</li> </ul>	
<b>Warnings</b>	
<b>Allergy alert:</b> Do not use if you are allergic to ranitidine or other acid reducers	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• 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.</li> <li>• with other acid reducers</li> <li>• if you have kidney disease, except under the advice and supervision of a doctor</li> </ul>	
<b>Ask a doctor before use if you have</b>	
<ul style="list-style-type: none"> <li>• had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>• heartburn with lightheadedness, sweating or dizziness</li> <li>• chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>• frequent chest pain</li> <li>• frequent wheezing, particularly with heartburn</li> <li>• unexplained weight loss</li> <li>• nausea or vomiting</li> <li>• stomach pain</li> </ul>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>• your heartburn continues or worsens</li> <li>• you need to take this product for more than 14 days</li> </ul>	
<b>If pregnant or breast-feeding,</b> ask a health professional before use.	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• adults and children 12 years and over:                             <ul style="list-style-type: none"> <li>• to relieve symptoms, swallow 1 tablet with a glass of water</li> <li>• to prevent symptoms, swallow 1 tablet with a glass of water <b>30 to 60 minutes before</b> eating food or drinking beverages that cause heartburn</li> <li>• can be used up to twice daily (do not take more than 2 tablets in 24 hours)</li> </ul> </li> <li>• children under 12 years: ask a doctor</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• do not use if printed foil under bottle cap is open or torn</li> <li>• do not use if individual foil packet is open or torn</li> <li>• store at 20°-25°C (68°-77°F)</li> <li>• avoid excessive heat or humidity</li> <li>• this product is sodium and sugar free</li> </ul>	

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

**75 TABLETS  
(75 DOSES)**

LOT  
EXP

ZANTAC does not supply store brands

**Drug Facts (continued)**

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

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

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

 **Boehringer  
Ingelheim**   Boehringer Ingelheim Consumer Health Care Products  
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**FDA STANDARD FORMAT COPY**

**STANDARD FORMAT/ HELVETICA NEUE 100% SCALE**

- DRUG FACTS – 9.1 PT HELVETICA NEUE BOLD CONDENSED ITALIC
- DRUG FACTS (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 – 85%
- BULLETS – 5 PT
- MM ■ 3/64" -Gap (Border -type)

**Boehringer Ingelheim**

**Copy for NDA Submission**

Product:  
**Zantac 150®**

Component:  
**150 mg 78ct Bottle Carton**

Date:  
**September 2015**


78



174

Zantac  
MAXIMUM STRENGTH

BONUS! 13 FREE TABLETS  
BONUS! 13 FREE TABLETS

Zantac  
MAXIMUM STRENGTH  
150  
Ranitidine Tablets 150 mg/Acid Reducer

090321410/4  
P027681-006  
CT6138A  
8/15 004


Zantac  
MAXIMUM STRENGTH  
150  
Ranitidine Tablets 150 mg/Acid Reducer  
78 TABLETS (78 DOSES)

**Drug Facts**

<b>Active ingredient (in each tablet)</b> Ranitidine 150 mg (as ranitidine hydrochloride 168 mg)	<b>Purpose</b> Acid reducer
<b>Uses</b> • 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	
<b>Warnings</b> <b>Allergy alert:</b> Do not use if you are allergic to ranitidine or other acid reducers	
<b>Do not use</b> • 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	
<b>Ask a doctor before use if you have</b> • 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	
<b>Stop use and ask a doctor if</b> • your heartburn continues or worsens      • you need to take this product for more than 14 days	
<b>If pregnant or breast-feeding</b> , ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • adults and children 12 years and over: • to relieve symptoms, swallow 1 tablet with a glass of water • to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn • can be used up to twice daily (do not take more than 2 tablets in 24 hours) • children under 12 years: ask a doctor	
<b>Other information</b> • 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	
<b>Inactive ingredients</b> hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, triacetin	


6 81421 03134 9

LOT      EXP

ZANTAC does not supply store brands

**Drug Facts (continued)**

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


Read the directions, consumer information leaflet 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 – 9.1 PT HELVETICA NEUE BOLD CONDENSED ITALIC  
 DRUG FACTS (continued) – 9.1 PT HELVETICA NEUE BOLD CONDENSED ITALIC  
 HEADINGS – 8 PT HELVETICA NEUE BOLD CONDENSED ITALIC  
 SUBHEADS – 6/6.25 PT HELVETICA NEUE BOLD CONDENSED  
 ALL SMALL TEXT – 6/6.25 PT HELVETICA NEUE CONDENSED  
 HEAVY RULE – 2.5 PT  
 LIGHT RULE – .5 PT  
 HORIZONTAL SCALE – 85%  
 BULLETS – 5 PT  
 MM ■ 3/64" -Gap (Border -type)

 **Boehringer  
Ingelheim**

**Copy for NDA  
Submission**

Product:  
**Zantac 150®**

Component:  
**150 mg 90ct  
Twin Bottle Label**

Date:  
**September 2015**

**What you should know about MAXIMUM STRENGTH Zantac 150®**

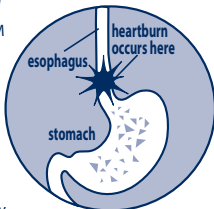
(Please read all of this information before taking MAXIMUM STRENGTH Zantac 150. Save this for future reference.)

**What is MAXIMUM STRENGTH Zantac 150?**

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

**Excellent Safety Record**

• The ingredient in MAXIMUM STRENGTH Zantac 150, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 has been taken safely with many frequently prescribed medications.



• MAXIMUM STRENGTH Zantac 150 tablets are sodium and sugar free.

**What symptoms does MAXIMUM STRENGTH Zantac 150 relieve and prevent?**

• MAXIMUM STRENGTH Zantac 150 relieves and prevents heartburn associated with acid indigestion and sour stomach.  
• 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 MAXIMUM STRENGTH Zantac 150?**

• To relieve symptoms, swallow 1 tablet with a glass of water.  
• To prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn.  
• This medicine can be used up to twice daily (do not take more than 2 tablets in 24 hours).  
• MAXIMUM STRENGTH Zantac 150 should not be given to children under 12 years old unless directed by a doctor.  
• Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers.

**How does MAXIMUM STRENGTH Zantac 150 work?**

• MAXIMUM STRENGTH Zantac 150 reduces the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

**Tips for managing heartburn**

• Do not lie flat or bend over soon after eating  
• Do not eat late at night, or just before bedtime  
• Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables.  
• Eat slowly and do not eat big meals  
• If you are overweight, lose weight  
• If you smoke, quit smoking  
• Raise the head of your bed  
• Wear loose fitting clothing around your stomach

**When should I see a doctor?**

• **Do not use**  
• if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.  
• with other acid reducers  
• if you have kidney disease, except under the advice and supervision of a doctor

• **Ask a doctor before use if you have**  
• had heartburn over 3 months. This may be a sign of a more serious condition.  
• heartburn with **lightheadedness, sweating or dizziness**  
• chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness  
• frequent **chest pain**  
• frequent wheezing, particularly with heartburn  
• unexplained weight loss  
• nausea or vomiting  
• stomach pain

• **Stop use and ask a doctor if**  
• your heartburn continues or worsens  
• you need to take this product for more than 14 days

• **If pregnant or breast-feeding**, ask a healthcare professional before use.

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

Drug Facts	
<b>Active ingredient (in each tablet)</b> Ranitidine 150 mg (as ranitidine hydrochloride 168 mg)	<b>Purpose</b> Acid reducer
<b>Uses</b>	
<ul style="list-style-type: none"> <li>relieves heartburn associated with acid indigestion and sour stomach</li> <li>prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages</li> </ul>	
<b>Warnings</b>	
<p><b>Allergy alert:</b> Do not use if you are allergic to ranitidine or other acid reducers</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>with other acid reducers</li> <li>if you have kidney disease, except under the advice and supervision of a doctor</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>heartburn with <b>lightheadedness, sweating or dizziness</b></li> <li>chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>frequent <b>chest pain</b></li> <li>frequent wheezing, particularly with heartburn</li> <li>unexplained weight loss</li> <li>nausea or vomiting</li> <li>stomach pain</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>your heartburn continues or worsens</li> <li>you need to take this product for more than 14 days</li> </ul> <p><b>If pregnant or breast-feeding</b>, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>adults and children 12 years and over: <ul style="list-style-type: none"> <li>to relieve symptoms, swallow 1 tablet with a glass of water</li> <li>to prevent symptoms, swallow 1 tablet with a glass of water <b>30 to 60 minutes</b> before eating food or drinking beverages that cause heartburn</li> <li>can be used up to twice daily (do not take more than 2 tablets in 24 hours)</li> </ul> </li> <li>children under 12 years: ask a doctor</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>do not use if printed foil under bottle cap is open or torn</li> <li>store at 20°-25°C (68°-77°F)</li> <li>avoid excessive heat or humidity</li> <li>this product is sodium and sugar free</li> </ul>	
<b>Inactive ingredients</b> hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, triacetin	
<p><b>Questions?</b> call 1-888-285-9159, (English/Spanish) M - F, 8:30 - 5 EST, or visit <a href="http://www.zantacotc.com">www.zantacotc.com</a></p>	



L6141A  
8/15 008  
P024906-007

090321341/6

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

**90 TABLETS (90 DOSES)**



**Zantac**  
MAXIMUM STRENGTH

**Twin Pack 2 Bottles X 45ct = 90ct**

**FDA STANDARD FORMAT COPY**

**STANDARD FORMAT/ HELVETICA NEUE 94% SCALE**

DRUG FACTS – 10 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)

 <p><b>Boehringer Ingelheim</b></p>
<p><b>Copy for NDA Submission</b></p>
<p>Product: <b>Zantac 150®</b></p>
<p>Component: <b>150 mg 100ct Twin Bottle Carton</b></p>
<p>Date: <b>September 2015</b></p>

**MAXIMUM STRENGTH  
Zantac  
150**

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

**100 TABLETS  
(100 DOSES)**



**2 bottles x 50ct = 100ct**

**TWIN PACK**  
**2 bottles x 50ct = 100ct**

**Drug Facts**

**Active ingredient (in each tablet)**  
Ranitidine 150 mg (as ranitidine hydrochloride 168 mg)  
Acid reducer

**Uses**  
Relieves heartburn associated with acid indigestion and sour stomach 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 black stools.  
If you have had a serious condition, see your doctor.  
These may be signs of a serious condition.

**Do not use**  
If you have kidney disease, except under the advice and supervision of a doctor.  
If you have heartburn over 3 months. This may be a sign of a more serious condition.

**Ask a doctor before use if you have**  
Heartburn with lightheadedness, sweating or dizziness.  
Heartburn with pain in the chest, neck or shoulders.  
Frequent chest pain.  
Unexplained weight loss.

**Stop use and ask a doctor if**  
Your heartburn continues or worsens.  
You need to take this product for more than 14 days.

**If pregnant or breast-feeding, ask a health professional before use.**  
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**  
Adults and children 12 years and over:  
To relieve symptoms, swallow 1 tablet with a glass of water.  
To prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn.  
Can be used up to twice daily (do not take more than 2 tablets in 24 hours).

Children under 12 years: ask a doctor.

**Other Information**  
Do not use if printed foil under bottle cap is open or torn. • Store at 20°-25°C (68°-77°F).  
• Avoid excessive heat or humidity.  
• This product is sodium and sugar free.

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

**Questions?** Call 1-888-265-9159 (English/Spanish) M-F 8:30-5 EST, or visit [www.zantac.com](http://www.zantac.com)

Boehringer Ingelheim Consumer Health Care Products Division of  
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877  
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All rights reserved. Product of Spain. Manufactured in Mexico.

**Drug Facts (continued)**

**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**  
Synthetic iron oxide, titanium dioxide, triacetin, hypromellose, magnesium stearate, microcrystalline cellulose.

**Questions?** Call 1-888-265-9159 (English/Spanish) M-F 8:30-5 EST, or visit [www.zantac.com](http://www.zantac.com)

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Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877  
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**MAXIMUM STRENGTH  
Zantac  
150**  
Ranitidine Tablets 150 mg/Acid Reducer

**100 TABLETS  
(100 DOSES)**

**LOT** \_\_\_\_\_  
**EXP** \_\_\_\_\_

ZANTAC does not supply state barcodes

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

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(100 DOSES)**

**LOT** \_\_\_\_\_  
**EXP** \_\_\_\_\_

ZANTAC does not supply state barcodes

**FDA STANDARD FORMAT COPY**  
**STANDARD FORMAT/ HELVETICA NEUE 75% SCALE**

DRUG FACTS – 10 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 – 85%  
BULLETS – 5 PT  
MM ■ 3/64" -Gap (Border -type)

**Boehringer Ingelheim**

**Copy for NDA Submission**

Product:  
**Zantac 150®**

Component:  
**150 mg Consumer Leaflet**

Date:  
**September 2015**

**Boehringer Ingelheim**

**What you should know about MAXIMUM STRENGTH Zantac**  
RANITIDINE TABLETS 150 mg 150®  
ACID REDUCER

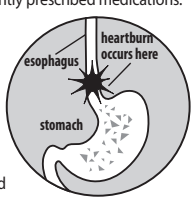
(Please read all of this information before taking MAXIMUM STRENGTH Zantac 150. Save this leaflet for future reference.)

**What is MAXIMUM STRENGTH Zantac 150?**  
**Excellent Safety Record**

**What symptoms does MAXIMUM STRENGTH Zantac 150 relieve and prevent?**


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

- MAXIMUM STRENGTH Zantac 150 contains 150 mg of ranitidine (as ranitidine hydrochloride, 168 mg), a medicine that doctors have prescribed more than 200 million times worldwide.
- The ingredient in MAXIMUM STRENGTH Zantac 150, ranitidine, has been prescribed by doctors for years to treat millions of patients safely and effectively. The active ingredient in MAXIMUM STRENGTH Zantac 150 has been taken safely with many frequently prescribed medications.
- MAXIMUM STRENGTH Zantac 150 tablets are sodium and sugar free.
- MAXIMUM STRENGTH Zantac 150 relieves and prevents heartburn associated with acid indigestion and sour stomach.
- Certain foods or beverages, and even lying down to sleep can cause heartburn associated with acid indigestion and sour stomach. It is normal for the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause burning pain and discomfort.
- To **relieve** symptoms, swallow 1 tablet with a glass of water.
- To **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn.
- This medicine can be used up to twice daily (do not take more than 2 tablets in 24 hours).
- MAXIMUM STRENGTH Zantac 150 should not be given to children under 12 years old unless directed by a doctor.
- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers.



**MANUFACTURER'S COUPON** OFFER EXPIRES 12/31/2018

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



090340616/3

**How does MAXIMUM STRENGTH Zantac 150 work?**

**Tips for managing heartburn**

**When should I see a doctor?**

MAXIMUM STRENGTH Zantac 150 reduces the production of stomach acid. This is what makes MAXIMUM STRENGTH Zantac 150 different from antacids, which neutralize the acid already in your stomach. Antacids do not reduce the production of acid.

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

**Do not use**

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers
- if you have kidney disease, except under the advice and supervision of a doctor

**Ask a doctor before use if you have**

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

**Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days

**If pregnant or breast-feeding**, ask a 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](http://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 the individual foil packet is open or torn.**

IT6583A  
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 880060, El Paso, TX 88588-0060. Improper use constitutes fraud. Copyright © 2014, Boehringer Ingelheim Pharmaceuticals, Inc. All rights reserved.

0681421-030596



 Boehringer Ingelheim
<b>Copy for NDA Submission</b>
Product: <b>Zantac 150®</b>
Component: <b>150 mg 45ct Bottle Label</b>
Date: <b>April 2015</b>




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 ■

 <b>Boehringer Ingelheim</b>
<b>Copy for NDA Submission</b>
Product: <b>Zantac 150®</b>
Component: <b>150 mg 78ct Bottle Label</b>
Date: <b>April 2015</b>

**Warnings** Do not use • if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. • with other acid reducers • if you have kidney disease, except under the advice and supervision of a doctor. **Ask a doctor before use if you have** • had heartburn over 3 months. • heartburn with **lightheadedness, sweating or dizziness** • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness • frequent **chest pain** • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain. **Stop use and ask a doctor if** • your heartburn worsens or you need to take this product for more than 14 days. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

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

MAXIMUM STRENGTH  
**Zantac**  
150




**78 ~~65~~**  
TABLETS  
(78 DOSES)

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

**Directions** • adults and children 12 years and over: to relieve symptoms, swallow 1 tablet with a glass of water. • to prevent symptoms, swallow 1 tablet with a glass of water 30 to 60 minutes before eating food or drinking beverages that cause heartburn • can be used up to twice daily (do not take more than 2 tablets in 24 hours) • children under 12 years: ask a doctor. **Questions?** call 1-888-285-9159 (English/Spanish) M-F 8:30 - 5:55P or visit [www.zantacotic.com](http://www.zantacotic.com) Copyright © 2015, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. All rights reserved. L6139A 4/15 002 P033127-002

LOT  
EXP



273

100%

**Warnings** Do not use • if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. • with other acid reducers • if you have kidney disease, except under the advice and supervision of a doctor. **Ask a doctor before use if you have** • had heartburn over 3 months. • heartburn with **lightheadedness, sweating or dizziness** • chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness • frequent **chest pain** • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain. **Stop use and ask a doctor if** • your heartburn worsens or you need to take this product for more than 14 days. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

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

MAXIMUM STRENGTH  
**Zantac**  
150



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(78 DOSES)

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LOT  
EXP



273

200%

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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 ■