

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21698

LABELING

Bottle Carton and Blister Carton
Over-the-Counter (OTC) Zantac 150 (Ranitidine Tablets 150 mg)

Drug Facts

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

Uses

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

Warnings

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

Do not use

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

Ask a doctor before use if you have

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

Stop use and ask a doctor if

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

If pregnant or breast-feeding, ask a health professional before use.

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

Directions

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



Drug Facts (continued)

Other information

- do not use if printed foil under bottle cap is torn or open
- store at 20° – 25°C (68° – 77° F)
- avoid excessive heat or humidity
- this product is sugar free

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

Questions?

call **1-800-223-0182**, weekdays, 9AM – 5PM EST

Name and Place of Distributor

Dist: **PFIZER CONSUMER HEALTHCARE**, Morris Plains, NJ 07950 USA

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Expiration Date:

mm/yyyy

Net Quantity

XX Tablets (XX Doses)

LOT:

EXP:

CARTON FRONT:

"Zantac 150

Ranitidine tablets 150 mg/Acid Reducer

MAXIMUM STRENGTH"

"PREVENTS & RELIEVES HEARTBURN Associated with Acid Indigestion & Sour Stomach"

"XX Tablets"

Consumer Package Insert

Over-the-Counter (OTC) Zantac 150 (Ranitidine Tablets 150 mg)

FRONT

What you should know about
MAXIMUM STRENGTH Zantac 150™
Ranitidine Tablets 150 mg
Acid Reducer

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

What is MAXIMUM STRENGTH Zantac 150?

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

What symptoms does MAXIMUM STRENGTH Zantac 150 treat 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.

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 sugar free.

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.

BACK

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?

- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers
- **Do not use**
 - if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor
 - with other acid reducers
 - if you have kidney disease, except under the advice and supervision of a doctor
- **Ask a doctor before use if you have**
 - had heartburn over 3 months. This may be a sign of a more serious condition.
 - heartburn with **lightheadedness, sweating or dizziness**
 - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 - frequent **chest pain**
 - frequent wheezing, particularly with heartburn
 - unexplained weight loss
 - nausea or vomiting
 - stomach pain

- **Stop use and ask a doctor if**
 - your heartburn continues or worsens
 - you need to take this product for more than 14 days
- **If pregnant or breast-feeding**, ask a health professional before use.
- **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Questions? Call 1-800-223-0182, weekdays, 9AM-5 PM EST www.prodhelp.com

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

BLISTERS: Do not use if the individual blister unit is open or torn.

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Morris Plains, NJ 07950 USA

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1 Tablet Pouch

Over-the-Counter (OTC) Zantac 150 (Ranitidine Tablets 150 mg)

READ THE DIRECTIONS AND WARNINGS BEFORE USE.

Active ingredient (in each tablet) Ranitidine 150 mg (as ranitidine hydrochloride 168 mg) **Purpose** Acid reducer **Uses** • relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach brought on by 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 • bloody or black stools. These may be signs of a serious condition. See your doctor. • kidney disease, except under the advice and supervision of a doctor. **Ask a doctor before use if you have** • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with **lightheadedness, sweating or dizziness** • chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness • frequent **chest pain** • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain. **Stop use and ask a doctor if** • your heartburn continues or worsens • you need to take this product for more than 14 days. **If pregnant or breast-feeding**, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions** • adults and children 12 years and over: • to **relieve** symptoms, swallow 1 tablet with a glass of water • to **prevent** symptoms, swallow 1 tablet with a glass of water **right 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 individual packet is open or torn • store at 20°- 25° C (68°- 77° F) • avoid excessive heat or humidity • this product is sugar free **Inactive ingredients** hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, triacetin **Questions?** call **1-800-223-0182**, weekdays, 9 AM – 5 PM EST

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Please note:

- Headings will be in contrasting color distinct from other text.
- Debossed “LOT XXXXXX EXP MM/YYYYY” will be added during packaging.

Draft Labeling Text – Bottle Label

Over-the-Counter (OTC) Zantac 150 (Ranitidine Tablets 150 mg)

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

Active ingredient (in each tablet) Ranitidine 150 mg (as ranitidine hydrochloride 168 mg) **Purpose** Acid reducer **Uses** • relieves heartburn associated with acid indigestion and sour stomach • prevents heartburn associated with acid indigestion and sour stomach brought on by 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 • bloody or black stools. These may be signs of a serious condition. See your doctor. • kidney disease, except under the advice and supervision of a doctor. **Ask a doctor before use if you have** • had heartburn over 3 months. This may be a sign of a more serious condition. • heartburn with **lightheadedness, sweating or dizziness** • chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness • frequent **chest pain** • frequent wheezing, particularly with heartburn • unexplained weight loss • nausea or vomiting • stomach pain. **Stop use and ask a doctor if** • your heartburn continues or worsens • you need to take this product for more than 14 days. **If pregnant or breast-feeding**, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions** • adults and children 12 years and over: • to **relieve** symptoms, swallow 1 tablet with a glass of water • to **prevent** symptoms, swallow 1 tablet with a glass of water **right 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** • store at 20°- 25°C (68°- 77° F) • avoid excessive heat or humidity • this product is sugar free

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

LOT:

EXP:

Please note:

Headings will be in contrasting color distinct from other text.

Zantac
Famotidine Tablets 150 mg / 150 mg
MULTI-PURPOSE STRENGTH 150TM
ONE TABLET FOR HEARTBURN
ACID INDIGESTION

Zantac
Famotidine Tablets 150 mg / 150 mg
MULTI-PURPOSE STRENGTH 150TM
ONE TABLET FOR HEARTBURN
ACID INDIGESTION

Zantac
Famotidine Tablets 150 mg / 150 mg
MULTI-PURPOSE STRENGTH 150TM
ONE TABLET FOR HEARTBURN
ACID INDIGESTION

Zantac
Famotidine Tablets 150 mg / 150 mg
MULTI-PURPOSE STRENGTH 150TM
ONE TABLET FOR HEARTBURN
ACID INDIGESTION

Zantac
Famotidine Tablets 150 mg / 150 mg
MULTI-PURPOSE STRENGTH 150TM
ONE TABLET FOR HEARTBURN
ACID INDIGESTION

Zantac
Famotidine Tablets 150 mg / 150 mg
MULTI-PURPOSE STRENGTH 150TM
ONE TABLET FOR HEARTBURN
ACID INDIGESTION

Push through pressed side.
CRACK HERE.

Zantac
Famotidine Tablets 150 mg / 150 mg
MULTI-PURPOSE STRENGTH 150TM
ONE TABLET FOR HEARTBURN
ACID INDIGESTION

Zantac
Famotidine Tablets 150 mg / 150 mg
MULTI-PURPOSE STRENGTH 150TM
ONE TABLET FOR HEARTBURN
ACID INDIGESTION

Zantac
Famotidine Tablets 150 mg / 150 mg
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