 Boehringer Ingelheim
Copy for NDA Submission
Product: Zantac 150[®]
Component: 150 mg 90ct Bottle Carton
Date: September 2015

090xxxxxx/1
Pxxxxxx-001
CT6794A
3/16 001

90 TABLETS (90 DOSES)

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



**MAXIMUM STRENGTH
Zantac[®]
150**
Ranitidine Tablets 150 mg/Acid Reducer

VALUE SIZE 90 TABLETS

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LOT
EXP

ZANTAC does not supply store brands

Drug Facts

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

Uses

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

Warnings

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

Do not use

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

Ask a doctor before use if you have

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

Stop use and ask a doctor if

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

if pregnant or breast-feeding, ask a health professional before use.
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 hypromellose, magnesium stearate, microcrystalline cellulose, synthetic red iron oxide, titanium dioxide, triacetin

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

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Drug Facts (continued)


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.

 **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)

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Copy for NDA Submission
Product: Zantac 150®
Component: 150 mg 90ct Bottle Label
Date: September 2015



100%



200%

FDA NARRATIVE FORMAT COPY
NARRATIVE FORMAT/ HELVETICA NEUE 100% SCALE
HEADINGS – 5 PT HELVETICA NEUE BOLD CONDENSED ITALIC
SUBHEADS – 5 PT HELVETICA NEUE BOLD CONDENSED
ALL SMALL TEXT – 5 PT HELVETICA NEUE CONDENSED
HORIZONTAL SCALE – 75%
BULLETS – 5 PT
MM ■