



Copy for NDA Submission

Product:
Zantac 150®

Component:
**150 mg 90ct
Bottle Carton**

Date:
September 2015

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

LOT
EXP

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
Division of Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877
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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)



Copy for NDA Submission

Product:
Zantac 150®

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

Date:
September 2015

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 a doctor before use if you have • had heartburn over 3 months. • heartburn 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.

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 EST, or visit www.zantacotc.com Copyright © 2016, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT. All rights reserved. L6795A 3/16 001 Pxxxxx-001

PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

90 TABLETS (90 DOSES)

LOT

EXP

090xxxxx/1

364

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 a doctor before use if you have • had heartburn over 3 months. • heartburn 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.

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PREVENTS & RELIEVES HEARTBURN associated with acid indigestion and sour stomach

90 TABLETS (90 DOSES)

LOT

EXP

090xxxxx/1

364

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 ■