Copy for NDA Submission

Product: Zantac 150°

Component: 150 mg 90ct Bottle Carton

Date: September 2015

MAXIMUM STRENGTH

PREVENTS & RELIEVES
HEARTBURN
associated with
asid indigestion and sour stomach

TABLETS
(90 DOSES)
90

ZANTAC does not supply store brands

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

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.

Do not use if you have severe diarrhea. This may be a sign 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. See your doctor.

Chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness

Frequent
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

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

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Product of Spain. Manufactured in Mexico.
Zantac 150®

150 mg 90ct

Bottle Label

September 2015

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

Prevents & Relieves Heartburn associated with acid indigestion and sour stomach

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 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. 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.

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