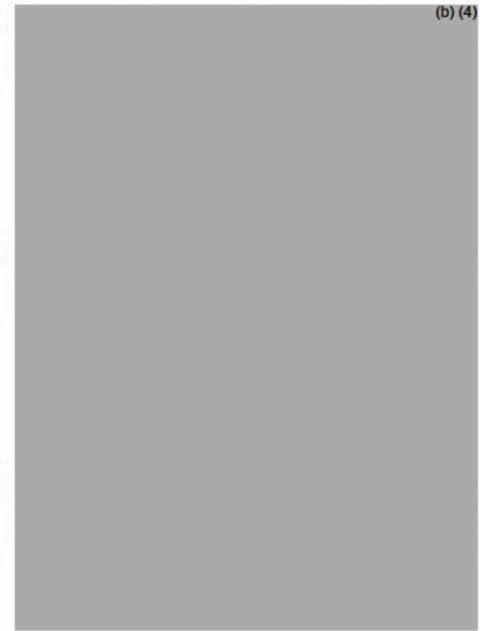


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022283Orig1s000

LABELING



(b) (4)

Sample Not for Sale

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EACH PACKET NET WT 0.192 (5.5g)

POWDER
PACKETS
2

Zegerid[®] OTC

Treats Frequent Heartburn

New

NDC 11523-7266-3

Lot No: _____

Exp. Date: _____

How Zegerid OTC Works for Your Frequent Heartburn

Zegerid OTC works differently from other OTC heartburn products, such as antacids and other acid reducers. Zegerid OTC stops acid production at the source - the acid pump that produces stomach acid. Zegerid OTC is to be used once a day (every 24 hours), every day for 14 days.

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 and 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

<p>Drug Facts (continued)</p> <p>DO NOT USE WITH OTHER LIQUIDS OR FOOD ■ stir well and drink immediately ■ refill cup with water and drink ■ do not use for more than 14 days unless directed by your doctor</p> <p>Repeated 14-Day Courses (if needed)</p> <p>■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p>	<p>Drug Facts (continued)</p> <p>Other information ■ each powder packet contains: sodium 460 mg ■ read the directions and warnings before use ■ keep the carton. It contains important information. ■ store between 20° to 25°C (68° to 77°F)</p> <p>■ tamper-evident: do not use if foil is open or broken ■ keep product out of high heat and humidity ■ protect product from moisture</p> <p>Inactive ingredients flavor, sucralose, sucrose, xanthan gum, xylitol</p>
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<p>Drug Facts</p> <p>Active ingredients (in each powder packet)</p> <p>Omeprazole 20 mg Acid reducer</p> <p>Sodium Bicarbonate 1680 mg Allows absorption of this omeprazole product</p> <p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn. This drug may take 1 to 4 days for full effect.</p> <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to omeprazole</p> <p>Do not use if you have: ■ trouble or pain swallowing food ■ vomiting with blood ■ bloody or black stools</p> <p>These may be signs of a serious condition. See your doctor.</p> <p>Ask a doctor before use if you have</p> <p>■ 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 ■ a sodium-restricted diet</p>	<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are taking</p> <p>■ warfarin, clopidogrel or cilostazol (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus (immune system medicine) ■ prescription antiretrovirals (medicines for HIV infection) ■ any other prescription drugs. Sodium bicarbonate may interact with certain prescription drugs.</p> <p>Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea</p> <p>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.</p> <p>Directions ■ for adults 18 years of age and older</p> <p>■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment</p> <p>■ product should be taken at least 1 hour before eating in the morning ■ take every day for 14 days ■ do not take more than once a day ■ empty packet contents into a small cup containing 2 tablespoons of WATER</p>
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Drug Facts

Active ingredients (in each powder packet)
Omeprazole 20 mg..... Acid reducer
Sodium Bicarbonate 1680 mg..... Allows absorption of this omeprazole product

Purpose

Use
■ treats frequent heartburn (occurs **2 or more** days a week)
■ not intended for immediate relief of heartburn. This drug may take 1 to 4 days for full effect.

Warnings

Allergy alert: Do not use if you are allergic to omeprazole.
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.

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
■ a sodium-restricted diet

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are taking
■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ diazepam (anxiety medicine)
■ digoxin (heart medicine)
■ tacrolimus (immune system medicine)
■ prescription antiretrovirals (medicines for HIV infection)
■ any other prescription drugs. Sodium bicarbonate may interact with certain prescription drugs.

Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea

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

■ for adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

Drug Facts (continued)

14-Day Course of Treatment
■ product should be taken at least 1 hour before eating in the morning
■ take every day for 14 days
■ do not take more than once a day
■ empty packet contents into a small cup containing 2 tablespoons of WATER
■ DO NOT USE WITH OTHER LIQUIDS OR FOOD
■ stir well and drink immediately
■ refill cup with water and drink
■ do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)
■ you may repeat a 14-day course every 4 months
■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.

Drug Facts (continued)

Other information
■ each powder packet contains: sodium 460 mg
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store between 20° to 25°C (68° to 77°F)
■ tamper-evident: do not use if foil is open or broken
■ keep product out of high heat and humidity
■ protect product from moisture

Inactive ingredients flavor, sucralose, sucrose, xanthan gum, xylitol

Questions or comments?
Call 1-888-4-ZEG-OTC (1-888-493-4682) between 8:00 AM and 5:00 PM Central Time, Monday through Friday or visit www.ZegeridOTC.com

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One 14-Day Course of Treatment
POWDER PACKETS
14
Zegerid OTC
Treats Frequent Heartburn
New
Omeprazole 20 mg/Acid Reducer
Sodium Bicarbonate 1680 mg/
Allows Absorption of this Omeprazole Product
Powder for Oral Suspension

POWDER PACKETS
14
Zegerid OTC
Treats Frequent Heartburn

LOT
EXP
NO INK NO VARNISH



How Zegerid OTC Works For Your Frequent Heartburn

Zegerid OTC works differently from other OTC heartburn products, such as antacids and other acid reducers. Zegerid OTC stops and prevents acid at the source - the acid pump that produces stomach acid. Zegerid OTC is to be used once a day (every 24 hours), every day for 14 days.

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 and 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

(b) (4)

READ OUTER CARTON FOR WARNINGS AND COMPLETE PRODUCT INFORMATION.

<p>Use</p> <ul style="list-style-type: none"> ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn. This drug may take 1 to 4 days for full effect. 	<p>Repeated 14-Day Courses (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
<p>Directions</p> <ul style="list-style-type: none"> ■ for adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours 	<p>Keep this and all medications out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
<p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ product should be taken at least 1 hour before eating in the morning ■ take every day for 14 days ■ do not take more than once a day ■ empty packet contents into a small cup containing 2 tablespoons of WATER ■ DO NOT USE WITH OTHER LIQUIDS OR FOOD ■ stir well and drink immediately ■ refill cup with water and drink ■ do not use for more than 14 days unless directed by your doctor 	<p>Other Information</p> <ul style="list-style-type: none"> ■ each powder packet contains sodium 460 mg ■ store between 20° to 25°C (68° to 77°F) ■ keep product out of high heat and humidity ■ protect product from moisture <p>© Copyright & Distributed by MSD Consumer Care, Inc., PO Box 377, Memphis, TN 38151 USA, a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ USA. All rights reserved. Product of Spain.</p> <p>XXXXXXXXXX/XX-XX-XXXX/XXXX-XXXX</p>

Treats Frequent Heartburn

Zegerid

OTC

DAILY DOSE

NET WT 0.19 OZ (5.6g)

SEE BACK FOR DIRECTIONS FOR USE

Powder for Oral Suspension

- Sodium Bicarbonate 1680 mg/
- Allows Absorption of this Omeprazole Product
- Omeprazole 20 mg/Acid Reducer

TAMPER EVIDENT: do not use if open or broken

TOP AT LINE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
06/17/2013