

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

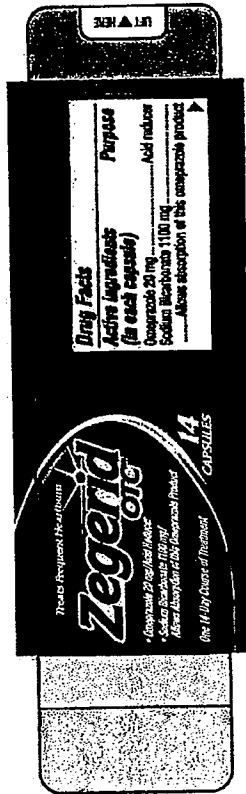
22-281

LABELING

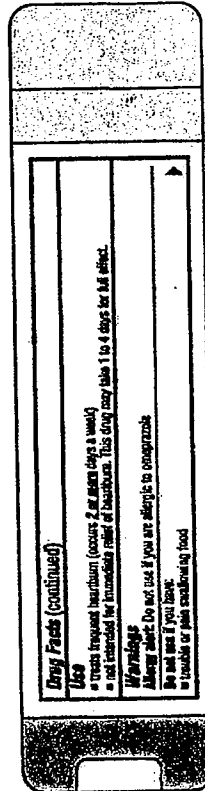
**ATTACH LEGEND ON ALL
DIGITAL MECHANICALS**

STANDARD FORMAT
 Helvetica Condensed
 Variable horizontal scale adheres to 39 characters
 per inch
Drug Facts - 9 pt Helvetica Cond. Bold Italic
Drug Facts (continued)
Drug Facts - 9 pt Helvetica Cond. Bold Italic
 (continued) - 8 pt Helvetica Cond.
Headings - 8 pt Helvetica Cond. Bold Italic
Sub-Headings - 6 pt Helvetica Cond. Bold
Text - 6 pt Helvetica Cond. minimum leading 6.5
Square Bullets - 3.5 pt Zapf Dingbats no compression
Border - 1 pt rule, JWG¹ pop all around
Baseline - 1 pt rule
Headline - 5 pt rule

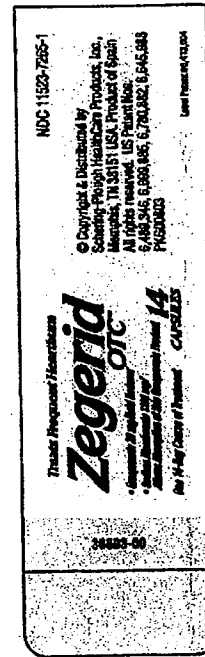
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 APC: PAS3-48
 14.22.88



A - Top Panel



B - Back Panel



Base Panel

Printable Text Area

Printable Text Area

3.25"

Drug Facts (continued)

- vomiting with blood
- bloody or black stools

These may be the signs of a serious condition. See your doctor.

- Ask a doctor before you use it if you have:
 - had heartburn over 3 months. This may be a sign of a more serious condition.
 - heartburn with lightheadedness, sweating or dizziness

C - Insert 1 Top

Drug Facts (continued)

- Ask a doctor or pharmacist before use if you are taking:
 - water pills (blood-thinning medicines)
 - prescription anti-ulcer or anti-yeast medicines
 - diuretics (water pills)
 - lithium (heart medicine)
 - tetracyclines (broad-spectrum antibiotics)
 - prescription anti-infective (medicines for HIV infection)
- any other prescription drugs. Sodium bicarbonate may interact with certain prescription drugs

E - Insert 2 Top

Drug Facts (continued)

Warnings

- Do not use for more than 14 days or more often than every 6 months unless directed by a doctor
- 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

14-Day Course of Treatment

- Swallow 1 capsule with a glass of water at least one hour before eating in the evening

G - Insert 3 Top

Drug Facts (continued)

- Do not use for more than 14 days or more often than every 6 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.

Other Information

- each capsule contains sodium bicarb

Base Panel

2.906"

Drug Facts (continued)

- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulder or lightheadedness
- fractured chest pain
- fractured ribs, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- a carbon-restricted diet

D - Insert 1 Back

Drug Facts (continued)

- 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
- fracture of 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.

F - Insert 2 Back

Drug Facts (continued)

- Take every day for 14 days
- Do not use more than 1 capsule a day
- Do not take if you are pregnant or breastfeeding
- Do not take if you are taking any other medicine
- Do not use for more than 14 days unless directed by your doctor
- Swallow 14-day course (1 capsule) every 4 months
- You may repeat a 14-day course every 4 months

H - Insert 3 Back

Drug Facts (continued)

- Store at 20°-25° (68°-77°)
- Keep out of reach of children
- Keep product out of high heat and humidity
- Protect product from moisture

ATLANTA (CONVENTIONAL AND PAPER) TRUCK
 4-88-256, 6-948-305, 6-780-882, 6-945-868
 PMS10003

Use 14-day Course of Treatment CAPSULES

Leaflet PMS10003

Drug Facts (continued)

- 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 is called a "stomach ache" and is caused by a stomach condition.

Other Information

- Each container contains between 600 mg
- Read for directions, warnings and accompanying label information before use

J - Insert 4 Back

Drug Facts (continued)

Active Ingredients
 cimetidine sodium, FD-C (also known as Tagamet), cimetidine sodium, pharmaceutical salt, polyethylene glycol, titanium dioxide

Directions (All Containers?)
 Call 1-888-428-2277 (1-888-428-4282) between 8:00 AM and 5:00 PM Eastern Standard Time, Monday through Friday or visit www.TagametOTC.com

L - Insert 5 Back

Drug Facts (continued)

Warnings
 • Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

Directions (All Containers?)
 Call 1-888-428-2277 (1-888-428-4282) between 8:00 AM and 5:00 PM Eastern Standard Time, Monday through Friday or visit www.TagametOTC.com

M - Insert 6 Top

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I - Insert 4 Top

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K - Insert 5 Top

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N - Insert 6 Back

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M - Insert 6 Top

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.

When to Expect When Using Zegerid OTC
 Zegerid OTC is a different type of heartburn medicine than other heartburn medicines. Zegerid OTC may take 1 to 4 days to feel effects, although some people get complete relief of symptoms within 24 hours. Make sure you take the entire 14 days of dosing to treat your frequent heartburn.

How to Zegerid OTC Solid
 Zegerid OTC is available in 14, 28 and 42 count doses. These doses contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and five 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

Other Information

- If you are overweight, lose weight.
- If you smoke, quit smoking.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.

NO INK/NO VARNISH

Drug Facts (continued)
Other Warnings:
 • Tell your doctor if you are taking any other medicines, especially with heartburn medicine, because there may be an interaction.
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Drug Facts (continued)
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Drug Facts
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PRINTSIDE GLUE

Treats Frequent Heartburn
Zegerid
 otc
 14 CAPSULES

New

Treats Frequent Heartburn
Zegerid
 otc
 14 CAPSULES

On a 14-Day Course of Treatment

Compare to Zegerid Prescription
Prescription Strength



LOT/EXP
 Area
 No Ink
 No Varnish



NO INK
 NO VARNISH

3.1497
 [80.00]

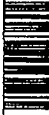
ATTACH LEGEND ON ALL DIGITAL MECHANICALS

STANDARD FORMAT
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 Variable Helvetica (same as above) to 38 characters per inch

Drug Facts - 9 pt Helvetica Cond. Bold Italic
 Drug Facts (continued)
 Drug Facts - 8 pt Helvetica Cond. Bold Italic (continued)
 Headline - 8 pt Helvetica Cond. Bold Italic
 Call Words - 8 pt Helvetica Cond. Bold
 Text - 8 pt Helvetica Cond. minimum 14.5/14.5
 Screen Pixels - 3.5 pt Caps (Digital) in compression
 Barcode - 1 pt Helvetica Cond. Bold
 Barcode - 5 pt Helvetica Cond. Bold

Created by:
 APD: PMA&D-09
 14.89.08

03658700



NO INK
NO VARNISH

Key Facts
 1. **Non-Aspirin Pain Relief** (For each capsule)
 2. **Reduces Stomach Acidity** (For each capsule)
 3. **Fastest-Acting Pain Relief** (For each capsule)
 4. **Reduces Stomach Acidity** (For each capsule)
 5. **Fastest-Acting Pain Relief** (For each capsule)

Warnings
 Do not use if you are allergic to aspirin, salicylic acid, or any of the other ingredients. Do not use if you have ever had an allergic reaction to aspirin, salicylic acid, or any of the other ingredients.

Directions
 Take one capsule every 4 to 6 hours as needed. Do not take more than 6 capsules in 24 hours.

Key Facts (continued)
 6. **Reduces Stomach Acidity** (For each capsule)
 7. **Fastest-Acting Pain Relief** (For each capsule)
 8. **Reduces Stomach Acidity** (For each capsule)
 9. **Fastest-Acting Pain Relief** (For each capsule)

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Directions
 Take one capsule every 4 to 6 hours as needed. Do not take more than 6 capsules in 24 hours.

Treats Frequent Heartburn
Zegerid
 otc
 28 CAPSULES

New
 Treats Frequent Heartburn
Zegerid
 otc
 28 CAPSULES
 • *Umpapazole 20 mg (Active Ingredient)*
 • *Acetylsalicylic Acid 100 mg (OTC)*
 Allows Absorption of this Unappreciable Product
 Turn 14-Day Courses of Treatment

OTC 28
Zegerid
 Treats Frequent Heartburn
 28 CAPSULES



LOT
 EXP
 A7-e0
 NO INK
 NO VARNISH

**FACH LEGEND ON ALL
 FACIAL MECHANICALS**
 FORWARD FORWARD
 Water-Resistant
 Washable
 Breathable
 Flexible
 Comfortable
 Secure
 Stable
 Skin-Friendly

03658500

Pharmaceutical Corporation
11th Street, New York, NY 10003
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Printed in the United States of America

NO INK
NO VARNISH



03658500

NO INK
NO VARNISH

Drug Facts

Active Ingredients: Famotidine (NDA 130-283-01)

Other Ingredients: Cellulose, croscarmellose sodium, hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyethylene glycol, sodium starch glycolate, xanthan gum.

Directions: Take 2 capsules 4 times a day, with or without food, for 14 days. If symptoms persist after 14 days, ask your doctor. Do not take more than 4 capsules in 24 hours. Do not take if you are taking other medicine containing famotidine.

Warnings: Do not take if you are taking other medicine containing famotidine. Tell your doctor if you are taking other medicine.

Other Information: This medicine contains 30 mg of famotidine per capsule.

Drug Facts (Continued)

Warnings (continued): Tell your doctor if you are taking other medicine containing famotidine. Tell your doctor if you are pregnant, planning to get pregnant, or are breastfeeding.

Other Information (continued): This medicine contains 30 mg of famotidine per capsule. Tell your doctor if you are pregnant, planning to get pregnant, or are breastfeeding.

Directions (continued): Take 2 capsules 4 times a day, with or without food, for 14 days. If symptoms persist after 14 days, ask your doctor. Do not take more than 4 capsules in 24 hours. Do not take if you are taking other medicine containing famotidine.

Other Information (continued): This medicine contains 30 mg of famotidine per capsule. Tell your doctor if you are pregnant, planning to get pregnant, or are breastfeeding.



LOT
EXP
Area
NO INK
NO VARNISH

Treats Frequent Heartburn

Zegerid

OTC

42 CAPSULES

New

• Omeprazole 20 mg Hard Capsules
• Sodium Bicarbonate 1100 mg†
• Also Contains Other OTC Ingredients

† Amount of sodium bicarbonate is based on 14 days of treatment.

Three 14-Day Courses of Treatment!

Treats Frequent Heartburn

Zegerid

OTC

42 CAPSULES