

ANDA # 201361
Final Printed Labeling
Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg
14 count Bottle Label

FA732D5F7 ELY 710

**NO PRINT
ON WHOLE
LABEL**

**CODE
AREA**
Shows through clear
from Table I.
(Varnish Over Code)

CLEAR OVERLAY LABEL

PEEL HERE

<p>Use</p> <ul style="list-style-type: none"> Take 1 to 4 capsules 1 to 4 days for full effect. Take 1 to 4 capsules 1 to 4 days for relief of heartburn. This drug may take 1 to 4 days for full effect. 	<p>Drug Facts</p> <p>Warnings</p> <ul style="list-style-type: none"> Do not use if you have: <ul style="list-style-type: none"> kidney or liver disease low sodium levels low potassium levels low calcium levels low magnesium levels low phosphorus levels low zinc levels low iron levels low copper levels low manganese levels low selenium levels low iodine levels low bromine levels low fluoride levels low chlorine levels low sulfur levels low nitrogen levels low oxygen levels low carbon levels low hydrogen levels low helium levels low neon levels low argon levels low krypton levels low xenon levels low radon levels low uranium levels low thorium levels low plutonium levels low americium levels low curium levels low berkelium levels low californium levels low einsteinium levels low fermium levels low mendelevium levels low nobelium levels low lawrencium levels low rutherfordium levels low dubnium levels low roentgenium levels low copernicium levels low nihonium levels low flerovium levels low livermorium levels low tennessine levels low oganesson levels 	<p>Directions</p> <ul style="list-style-type: none"> Swallow 1 capsule with a glass of water at least 1 hour before eating in the morning. Take every day for 14 days. Do not take more than 1 capsule a day. Do not chew or crush the capsule. Do not open capsule and sprinkle on food. Do not use for more than 14 days unless directed by your doctor. Repeat 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. 	<p>Other information</p> <ul style="list-style-type: none"> Keep out of reach of children. Do not use if the band around the capsule is missing or broken. Do not use if printed seal is broken. 	<p>Drug Facts (continued)</p> <p>Warnings</p> <ul style="list-style-type: none"> Do not use if you have: <ul style="list-style-type: none"> kidney or liver disease low sodium levels low potassium levels low calcium levels low magnesium levels low phosphorus levels low zinc levels low iron levels low copper levels low manganese levels low selenium levels low iodine levels low bromine levels low chlorine levels low sulfur levels low nitrogen levels low oxygen levels low carbon levels low hydrogen levels low helium levels low neon levels low argon levels low krypton levels low xenon levels low radon levels low uranium levels low thorium levels low plutonium levels low americium levels low curium levels low berkelium levels low californium levels low einsteinium levels low fermium levels low mendelevium levels low nobelium levels low lawrencium levels low rutherfordium levels low dubnium levels low roentgenium levels low copernicium levels low nihonium levels low flerovium levels low livermorium levels low tennessine levels low oganesson levels 	<p>How to use</p> <ul style="list-style-type: none"> Swallow 1 capsule with a glass of water at least 1 hour before eating in the morning. Take every day for 14 days. Do not take more than 1 capsule a day. Do not chew or crush the capsule. Do not open capsule and sprinkle on food. Do not use for more than 14 days unless directed by your doctor. Repeat 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. 	<p>Drug Facts (continued)</p> <p>Warnings</p> <ul style="list-style-type: none"> Do not use if you have: <ul style="list-style-type: none"> kidney or liver disease low sodium levels low potassium levels low calcium levels low magnesium levels low phosphorus levels low zinc levels low iron levels low copper levels low manganese levels low selenium levels low iodine levels low bromine levels low chlorine levels low sulfur levels low nitrogen levels low oxygen levels low carbon levels low hydrogen levels low helium levels low neon levels low argon levels low krypton levels low xenon levels low radon levels low uranium levels low thorium levels low plutonium levels low americium levels low curium levels low berkelium levels low californium levels low einsteinium levels low fermium levels low mendelevium levels low nobelium levels low lawrencium levels low rutherfordium levels low dubnium levels low roentgenium levels low copernicium levels low nihonium levels low flerovium levels low livermorium levels low tennessine levels low oganesson levels
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Front - Up to 6 colors

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(POB)

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<p>No Copy Area</p>	<p>Distributed By Perrigo Alegan, MI 49010</p> <p>Perrigo Treat & Prevent Heartburn Omeprazole and Sodium Bicarbonate Capsules, 20 mg/1100 mg • Acid Reducer • Allow Absorption of this Omeprazole Product 14 CAPSULES One 14-Day Course of Treatment</p>	<p>No Copy Area</p> <p>CODE AREA (with varnish) : 732D 5 FA F7</p>
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BASE - Up to 6 colors

MODIFIED FORMAT

TYPE SIZES:
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 7 pt Helvetica Neue 57 Condensed
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

3-10-16

MODIFIED FORMAT
TYPE SIZES:
 TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
 TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
 (continued) 7 pt Helvetica Neue 57 Condensed
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6, 4 and 6, 5 pt
BULLETS: 5 pt Square with 2 M's spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1, 5 pt
HAIRLINES: 0, 5 pt

EFB 1369
0073274CH

One 14-Day Course of Treatment

14 UNIT-DOSE CAPSULES

• Acid Reducer
 • Allows Absorption of this Omeprazole Product

Omeprazole and Sodium Bicarbonate Capsules, 20 mg/100 mg

Treats Frequent Heartburn

Perrigo

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DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

<p>Drug Facts</p> <p>Active ingredients (in each capsule) Purpose Omeprazole 20 mg.....Acid reducer Sodium Bicarbonate 100 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 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. These may be signs of a serious condition. See your doctor.</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin, clopidogrel or omeprazole (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ diazepam (anxiety medicine) ■ digoxin (heart medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicine) ■ prescription antiretrovirals (medicines for HIV infection) ■ methotrexate (arthritis medicine) ■ 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>Drug Facts (continued)</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 (1-800-222-1222).</p> <p>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</p> <p>14-Day Course of Treatment ■ swallow 1 capsule with a glass of water at least 1 hour before eating in the morning ■ take every day for 14 days ■ do not take more than 1 capsule a day ■ do not chew or crush the capsule ■ do not open capsule and sprinkle on food ■ do not use for more than 14 days unless directed by your doctor</p> <p>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</p> <p>■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other Information ■ each capsule contains: sodium 302 mg ■ read the directions, warnings and accompanying label information before use ■ store at 20-25°C (68-77°F) ■ tamper-evident: do not use if the band around the capsule is missing or broken. Do not use if blister unit is broken or torn. ■ keep product out of high heat and humidity ■ protect product from moisture</p>
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Drug Facts (continued)

inactive ingredients FD&C blue no. 1, FD&C blue no. 2 aluminum lake, FD&C red no. 40, gelatin, polyorbate 80, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, titanium dioxide

Drug Facts (continued)

Questions or comments?
 1-800-719-9260

Distributed By
Perrigo[®]
 Allegan, MI 49010

CODE AREA

1 73274 00 013

ANDA # 201361
Final Printed Labeling
Omeprazole and Sodium Bicarbonate Capsules, 20 mg/100 mg
14 count Carton (inner)