

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

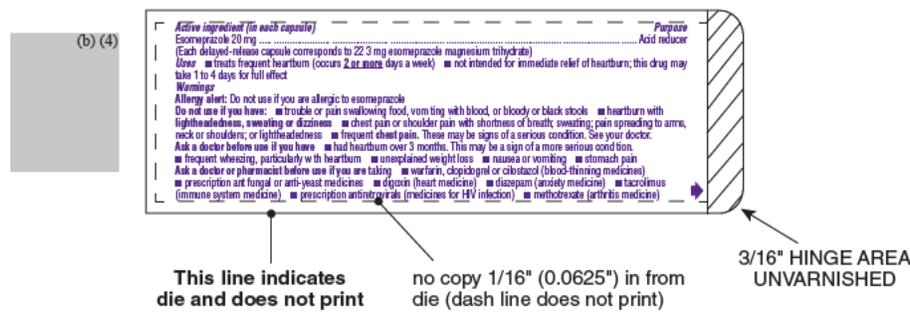
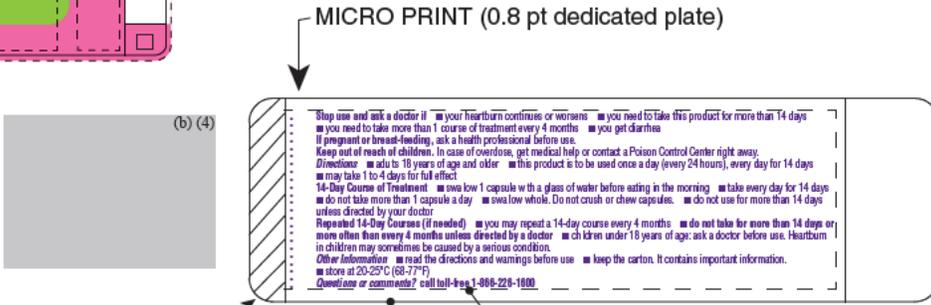
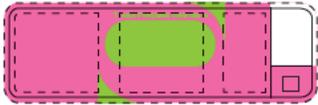
204655Orig1s000

LABELING

NOTE: the following labeling information was obtained from Drugs@FDA and NOT DARRTs as there was an issue with the version in DARRTs. The division is aware of this issue, but has not uploaded the correct version of the label into DARRTs. Therefore, per Carols instructions the Label information from Drugs@FDA has been saved



Gloss and Matt Varnish - Full size file on Varnish layer



PRODUCTION (NOT COLOR ACCURATE)



DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	4.5 pt
• SUBHEADINGS/BODY TEXT	4.5 pt
• LEADING	4.5 pt
• BULLETS	3.5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINE, HAIRLINES	1 pt, .5 pt

UNCOATED
NO COPY
NO PRINT

128 Code: 048361

128 CODE
AREA

128 Code: 048361

128 CODE
AREA

128 Code: 048361

128 CODE
AREA

MICRO PRINT

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Drug Facts

Active ingredient (in each capsule)
Esomeprazole 20 mg Acid reducer
(Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)

Purpose
Acid reducer

Uses
■ 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 esomeprazole

Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ 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
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.
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ stomach pain

Ask a doctor or pharmacist before use if you are taking
■ warfarin, clopidogrel or cilostazol (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ digoxin (heart medicine)
■ diazepam (anxiety medicine)
■ tacrolimus (immune system medicine)
■ prescription antiretrovirals (medicines for HIV infection)
■ methotrexate (arthritis medicine)

Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days

Drug Facts (continued)
■ 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
■ adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ may take 1 to 4 days for full effect

14-Day Course of Treatment
■ swallow 1 capsule with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 capsule a day
■ swallow whole. Do not crush or chew capsules.
■ 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 before use. Heartburn in children may sometimes be caused by a serious condition.

Other Information
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F)

Inactive ingredients corn starch, D&C red no. 28, FD&C blue no. 1, FD&C red no. 40, ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, pharmaceutical ink, polysorbate 80, sucrose, talc, titanium dioxide, triethyl citrate

Questions or comments?
call toll-free 1-866-226-1600



Marketed by:
Pfizer, Madison, NJ 07940 USA
© 2014 Pfizer Inc.
Made in France
For most recent product information, visit
www.Nexium24HR.com
Nexium and the colors purple and gold as applied to the capsule are registered trademarks of AstraZeneca AB and are used under license.

NEW

Treats Frequent Heartburn



2 CAPSULES

First two doses of a 14-day course of treatment.



Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or yellow band around the center of each capsule is broken or missing.

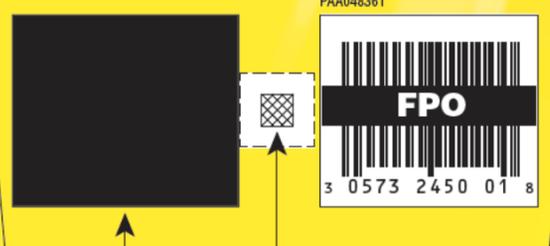
128 CODE
AREA

128 CODE AREA - SUBSET C 10 MIL DENSITY WITH 4 OR 6 DIGITS (CODE TO EXTEND TO EDGE OF FLAP - UNVARNISHED) PRINTED SIDE OF CARTON
128 Code: 048361

128 CODE
AREA

128 Code: 048361

MICRO PRINT



LOT & EXP AREA. DARK COLOR FOR LASER PRINTING.
3/16" DATA MATRIX CODE WITH 1/8" QUIET ZONE ON ALL SIDES
Data Matrix: 048361

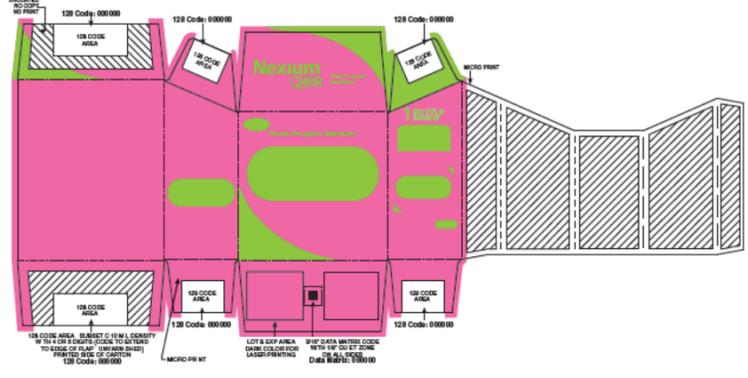
128 CODE
AREA

128 Code: 048361

PRODUCTION (NOT COLOR ACCURATE)

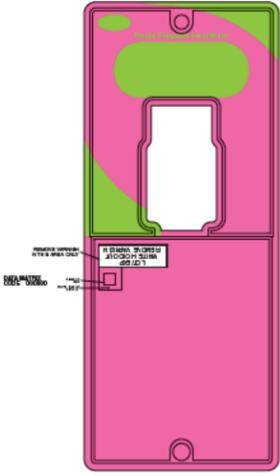


Gloss and Matt Varnish - Full size file on Varnish layer



DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Gloss and Matt Varnish -
Full size file on Varnish layers



REMOVE VARNISH
IN THIS AREA ONLY

DATA MATRIX
CODE = 048367

DATA MATRIX
CODE
WHITE HOLDOUT
QUIET AREA

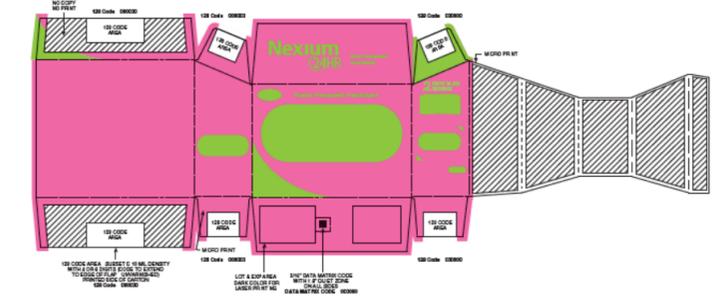
PRODUCTION

(NOT COLOR ACCURATE)

(b) (4)

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Gloss and Matt Varnish -
Full size file on Varnish layer



128 CODE AREA - SUBSET C 10 MIL DENSITY WITH 4 OR 6 DIGITS (CODE TO EXTEND TO EDGE OF FLAP - UNVARNISHED) PRINTED SIDE OF CARTON
128 Code = 048374

128 Code = 048374

LOT & EXP AREA. DARK COLOR FOR LASER PRINTING.

3/16" DATA MATRIX CODE WITH 1/8" QUIET ZONE ON ALL SIDES
DATA MATRIX CODE = 048374

128 Code = 048374

PRODUCTION (NOT COLOR ACCURATE)



DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

(b) (4)

UNCOATED
NO COPY
NO PRINT

128 CODES = 048372

128 CODE
AREA

128 CODE
AREA

128 CODE
AREA

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Drug Facts
Active ingredient (in each capsule) Esomeprazole 20 mg
Purpose Acid reducer
(Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)

Uses
■ 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 esomeprazole
Do not use if you have:
■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools
■ 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
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.
■ frequent wheezing, particularly with heartburn
■ unexplained weight loss
■ nausea or vomiting
■ stomach pain

Ask a doctor or pharmacist before use if you are taking
■ warfarin, clopidogrel or citalopram (blood-thinning medicines)
■ prescription antifungal or anti-yeast medicines
■ digoxin (heart medicine)
■ diazepam (anxiety medicine)
■ tacrolimus (immune system medicine)
■ prescription antiretroviral (medicines for HIV infection)
■ methotrexate (arthritis medicine)

Stop use and ask a doctor if
■ your heartburn continues or worsens
■ you need to take this product for more than 14 days

Drug Facts (continued)
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea

Directions
■ adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ may take 1 to 4 days for full effect

14-Day Course of Treatment
■ swallow 1 capsule with a glass of water before eating in the morning
■ take every day for 14 days
■ do not take more than 1 capsule a day
■ swallow whole. Do not crush or chew capsules.
■ do not use for more than 14 days unless directed by your doctor
■ 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

Other information
■ read the directions and warnings before use
■ keep the carton. It contains important information.
■ store at 20-25°C (68-77°F)

Inactive ingredients
corn starch, D&C red no. 28, FD&C blue no. 1, FD&C red no. 40, ferric oxide, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, pharmaceutical ink, polysorbate 80, sucrose, talc, titanium dioxide, triethyl citrate

Questions or comments?
call toll-free 1-866-226-1600

Tips for Managing Heartburn

- Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.



Marketed by:
Pfizer, Madison, NJ 07940 USA
© 2014 Pfizer Inc.
Made in France
For most recent product information, visit
www.Nexium24HR.com
Nexium and the colors purple and gold
as applied to the capsule are registered
trademarks of AstraZeneca AB and are
used under license.

Nexium[®]
24HR | Clinically Proven to
Treat Frequent Heartburn

NEW Treats Frequent Heartburn

Nexium[®]
(esomeprazole magnesium)
Delayed-Release Capsules
22.3 mg/Acid Reducer
24HR

42 CAPSULES
Three 14-day courses of treatment

May take 1 to 4 days for full effect

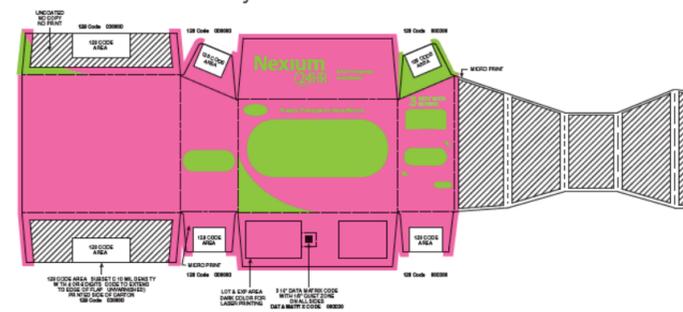
3 BOTTLES INSIDE



ACTUAL SIZE

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" or yellow band around the center of each capsule is broken or missing.

Gloss and Matt Varnish -
Full size file on Varnish layer



MICRO PRINT

128 CODE
AREA

128 CODE
AREA

128 CODE
AREA

MICRO PRINT

128 CODE AREA - SUBSET C 10 MIL DENSITY WITH 4 OR 6 DIGITS (CODE TO EXTEND TO EDGE OF FLAP - UNVARNISHED) PRINTED SIDE OF CARTON

LOT & EXP AREA. DARK COLOR FOR LASER PRINTING.

3/16" DATA MATRIX CODE WITH 1/8" QUIET ZONE ON ALL SIDES
DATA MATRIX CODE = 048372

PAA048372



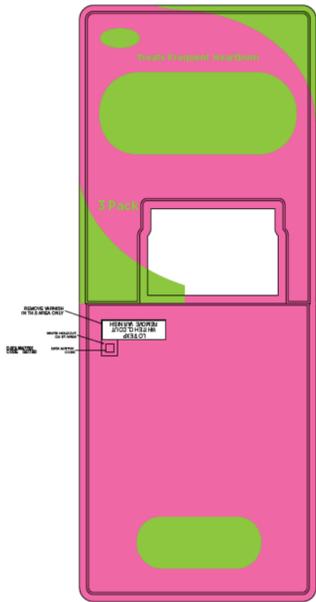
PRODUCTION



(b) (4)

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

Gloss and Matt Varnish - Full size file on Varnish layers



REMOVE VARNISH IN THIS AREA ONLY

WHITE HOLDOUT QUIET AREA

DATA MATRIX CODE = 048363

DATA MATRIX CODE

NEW

Treats Frequent Heartburn

Nexium®

(esomeprazole magnesium)
Delayed-Release Capsules **24HR**
22.3 mg/Acid Reducer

May take 1 to 4 days for full effect

3 Pack

42 CAPSULES
Three 14-day courses of treatment

REMOVE VARNISH

LOT/EXP

WHITE HOLDOUT

DATA MATRIX CODE

3 0573 2450 43 8

FPO

Marketed by: Pfizer, Madison, NJ 07940 USA
© 2014 Pfizer Inc.
Made in France
For most recent product information, visit www.Nexium24HR.com
Nexium and the colors purple and gold applied to the capsule are registered trademarks of AstraZeneca AB and are used under license.

Drug Facts (continued)

Active ingredient (in each capsule) Esomeprazole 20 mg (each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)

Uses
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
Do not use if you are allergic to esomeprazole
Trouble or pain swallowing food, vomiting with blood or bloody or black stools
Headache with dizziness, sweating or dizziness
Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arm, neck or shoulders, or lightheadedness
Ask a doctor or pharmacist before use if you are taking prescription antifungal or anti-yeast medicines
Warfarin, digoxin or clozapine (blood-thinning medicines)

Do not use if you have:
Headache or dizziness, sweating or dizziness
Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arm, neck or shoulders, or lightheadedness
Trouble or pain swallowing food, vomiting with blood or bloody or black stools

Ask a doctor before use if you have:
Headache or dizziness, sweating or dizziness
Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arm, neck or shoulders, or lightheadedness
Headache or dizziness, sweating or dizziness
Chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arm, neck or shoulders, or lightheadedness
Trouble or pain swallowing food, vomiting with blood or bloody or black stools

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

Other information
Keep the card. It contains important information.
Read the directions and warnings before use.
Store at 20-25°C (68-77°F).
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
Adults 18 years of age and older
This product is to be used once a day (every 24 hours), every day for 14 days
May take 1 to 4 days for full effect
14-Day Course of Treatment
Take one 14-day course every 4 months
Do not take for more than 14 days unless directed by your doctor
Do not use for more than 14 days unless directed by your doctor
Swallow whole. Do not crush or chew capsules.
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

Questions or comments?
Call toll-free 1-866-226-1600
Nexium and the colors purple and gold applied to the capsule are registered trademarks of AstraZeneca AB and are used under license.

KEEP CARD FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

Do Not Use if seal under bottle cap printed with "SEALED for YOUR PROTECTION" or yellow band around the center of each capsule is broken or missing.

Tips for Managing Heartburn
Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol, and carbonated beverages.
Eat slowly and do not eat big meals.
Do not eat late at night or just before bedtime.
Do not lie flat or bend over soon after eating.
Rise the head of your bed.
Wear loose-fitting clothing around your stomach.
If you are overweight, lose weight.
If you smoke, quit smoking.

PRODUCTION

(NOT COLOR ACCURATE)

(b) (4)

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	10 pt
• DRUG FACTS CONTINUED	9 pt
• HEADINGS	9 pt
• SUBHEADINGS/BODY TEXT	7 pt
• LEADING	7.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	6 pt
• SPACE BEFORE BULLET	N/A
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

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

/s/

THERESA M MICHELE
03/28/2014