

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**207920Orig1s000**

**LABELING**

**TOP (FACE) PANEL 1**

NO COPY 1/16" (0.0625") IN FROM DIE (DASH LINE DOES NOT PRINT)

THIS LINE INDICATES DIE AND DOES NOT PRINT

KISS CUT

UNVARNISHED AND PRINTED IN BLACK FOR LOT & EXPIRATION AREA

ART BLEEDS OFF 1/16" (0.0625") OUT FROM DIE (DASH LINE DOES NOT PRINT)

0.125" X 0.125" DATA MATRIX CODE (ECC 200), PRINTED IN BLACK ON UNPRINTED WHITE BACKGROUND  
**DATA MATRIX CODE = 058427**

Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.

Marketed by: Pfizer, Madison, NJ 07940 USA © 2015 Pfizer Inc. Made in France. For most recent product information, visit www.Nexium24HR.com. PAA058427-FDA03

Treats Frequent Heartburn

**Nexium<sup>®</sup>**  
 esomeprazole delayed-release tablets 20 mg/acid reducer **24HR**

May take 1 to 4 days for full effect  
**2 TABLETS**  
 SAMPLE - NOT FOR SALE

KEEP CARTON FOR COMPLETE WARNINGS AND IMPORTANT INFORMATION.

LIFELINE For More Information

**BASE PANEL 3**

1/4" HINGE AREA UNVARNISHED (LINES DO NOT PRINT)

NO COPY 1/16" (0.0625") IN FROM DIE (DASH LINE DOES NOT PRINT)

ART BLEEDS OFF 1/16" (0.0625") OUT FROM DIE (DASH LINE DOES NOT PRINT)

KISS CUT

THIS LINE INDICATES DIE AND DOES NOT PRINT

(b) (4)

(Immune system medicines) ■ 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 ■ 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 tablet with a glass of water before eating in the morning ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ swallow whole. Do not crush or chew tablets. ■ 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)

**Questions or comments?** call toll-free: weekdays 9 AM to 5 PM EST at 1-866-226-1600

**TOP (BACK) PANEL 2**

NO COPY 1/16" (0.0625") IN FROM DIE (DASH LINE DOES NOT PRINT)

ART BLEEDS OFF 1/16" (0.0625") OUT FROM DIE (DASH LINE DOES NOT PRINT)

1/4" HINGE AREA UNVARNISHED (LINES DO NOT PRINT)

THIS LINE INDICATES DIE AND DOES NOT PRINT

(b) (4)

**Active ingredient (in each tablet)**

Esomeprazole 20 mg ..... Purpose<sup>1</sup>  
 Acid reducer

<sup>1</sup>Each delayed-release tablet 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

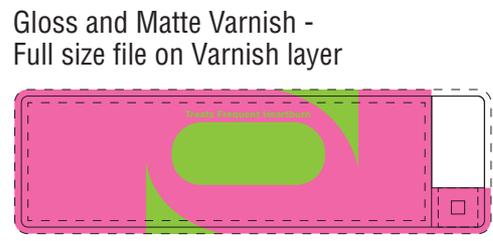
**Do not use if you have:** ■ trouble or pain swallowing food, vomiting with blood, or bloody or black stools ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent 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 clobazam (blood-thinning medicines) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ diazepam (anxiety medicine) ■ tacrolimus or mycophenolate mofetil

**PRODUCTION** (NOT COLOR ACCURATE)

Job Information	Color Legend
(b) (4)	



DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	5.5 pt
• SUBHEADINGS/BODY TEXT	5.5 pt
• LEADING	5.5 pt
• BULLETS	4.5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINE, HAIRLINES	1 pt, .5 pt

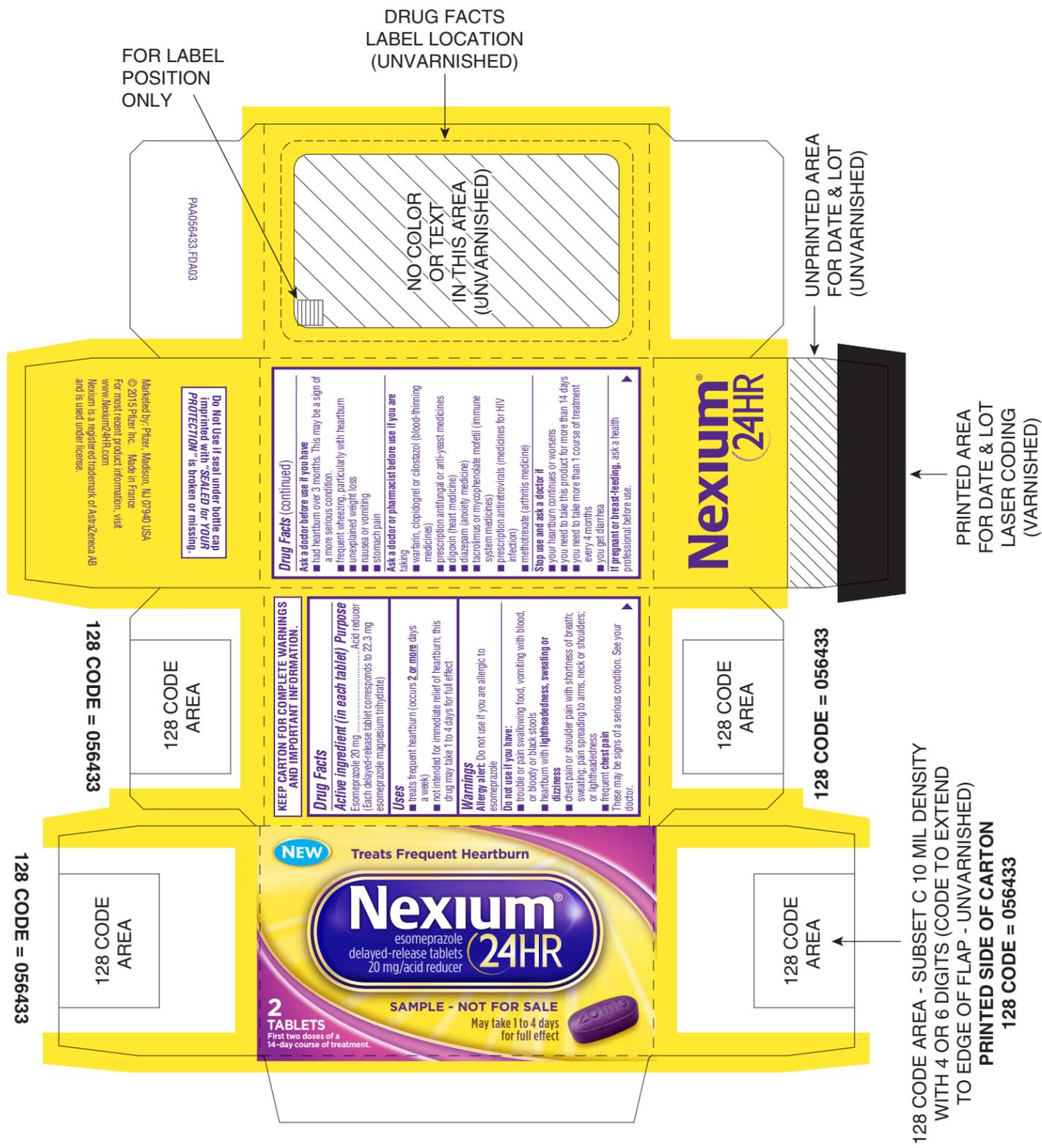
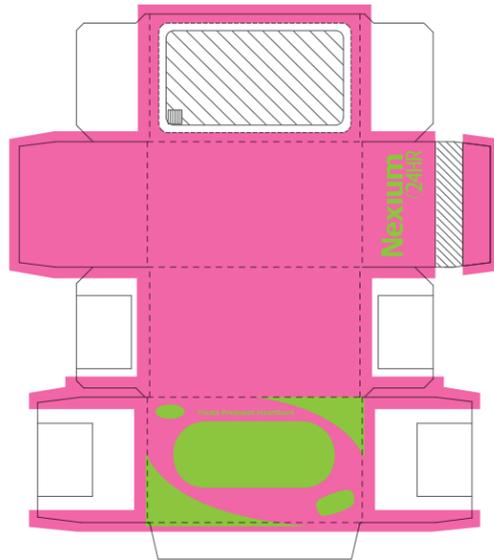
DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
• DRUG FACTS CONTINUED	8 pt
• HEADINGS	8 pt
• SUBHEADINGS/BODY TEXT	6 pt
• LEADING	6.5 pt
• # OF CHARACTERS PER INCH	<39
• BULLETS	5 pt
• SPACE BEFORE BULLET	2 ems
• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

**PRODUCTION**

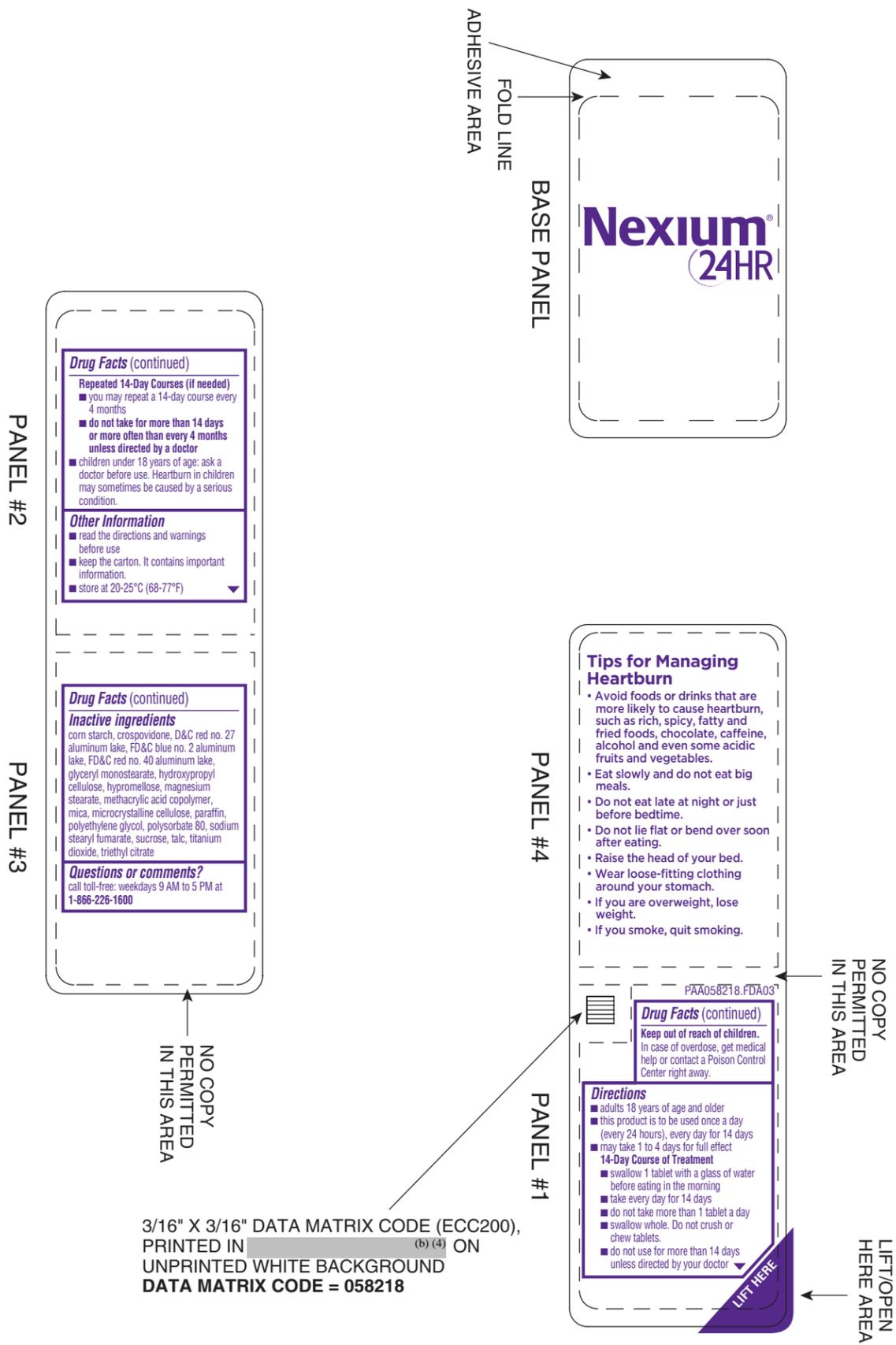
(NOT COLOR ACCURATE)

Job Information	Color Legend
(b) (4)	

Gloss and Matte 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 = 056433



**PRODUCTION**

(NOT COLOR ACCURATE)

Job Information	Color Legend
(b) (4)	

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	N/A
• 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

**TOP (FACE)  
PANEL 1**



KISS CUT

UNVARNISHED AND PRINTED IN BLACK FOR LOT & EXPIRATION AREA

ART BLEEDS OFF 1/16" (0.0625") OUT FROM DIE (DASH LINE DOES NOT PRINT)

0.125" X 0.125" DATA MATRIX CODE (ECC 200), PRINTED IN BLACK ON UNPRINTED WHITE BACKGROUND  
**DATA MATRIX CODE = 069163**

1/4" HINGE AREA UNVARNISHED (LINES DO NOT PRINT)

KISS CUT

**BASE  
PANEL 3**



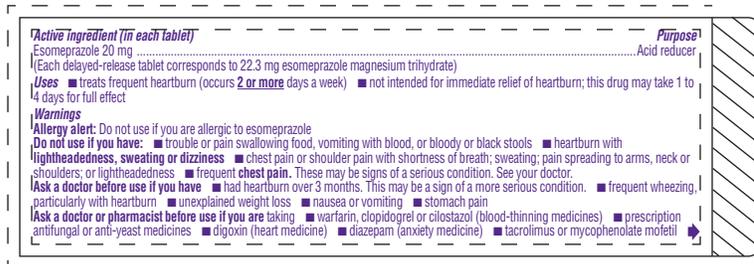
ART BLEEDS OFF 1/16" (0.0625") OUT FROM DIE (DASH LINE DOES NOT PRINT)

THIS LINE INDICATES DIE AND DOES NOT PRINT

NO COPY 1/16" (0.0625") IN FROM DIE (DASH LINE DOES NOT PRINT)

(b) (4)

**TOP (BACK)  
PANEL 2**



THIS LINE INDICATES DIE AND DOES NOT PRINT

(b) (4)

1-1/16" (0.0625") CORNER RADIUS TYP

**PRODUCTION (NOT COLOR ACCURATE)**

Job Information	Color Legend
(b) (4)	

Gloss and Matte Varnish - Full size file on Varnish layer



DRUG FACTS TEXT DEFINED	TYPE SIZE
• HEADINGS	5.5 pt
• SUBHEADINGS/BODY TEXT	5.5 pt
• LEADING	5.5 pt
• BULLETS	4.5 pt
• SPACE BEFORE BULLET	2 ems
• WARNING BOX LINE, HAIRLINES	1 pt, .5 pt

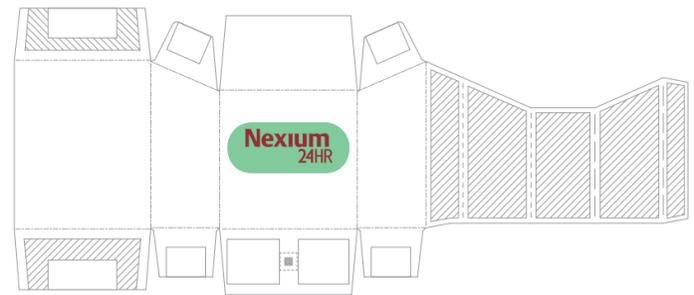


128 CODE AREA - SUBSET C 10 MIL DENSITY WITH 4 OR 6 DIGITS (CODE TO EXTEND TO EDGE OF FLAP - UNVARNISHED) PRINTED SIDE OF CARTON  
128 Code: 069162

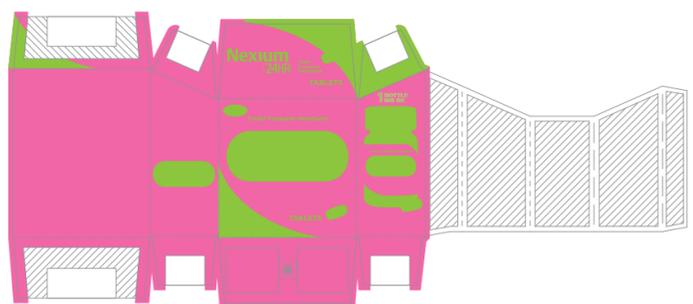
MICRO PRINT

LOT & EXP AREA. DARK COLOR FOR LASER PRINTING.  
3/16" DATA MATRIX CODE WITH 1/8" QUIET ZONE ON ALL SIDES  
Data Matrix: 069162

Emboss - Full size file on Emboss layer\*  
\* There are two levels of Embossing.



Gloss and Matte Varnish - Full size file on Varnish layer

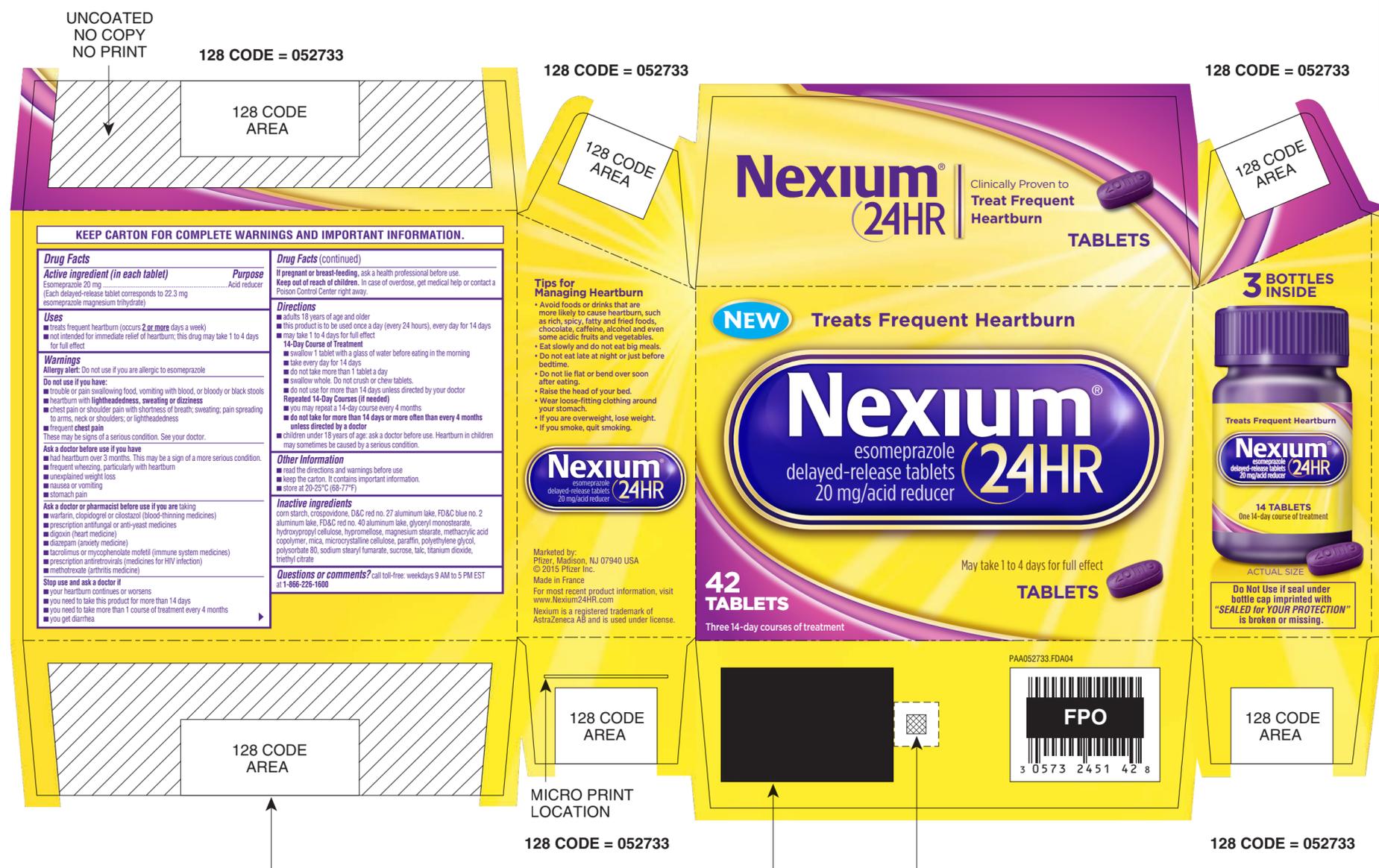


**PRODUCTION** (NOT COLOR ACCURATE)

Job Information	Color Legend

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





UNCOATED  
NO COPY  
NO PRINT

128 CODE = 052733

128 CODE  
AREA

128 CODE = 052733

128 CODE  
AREA

128 CODE = 052733

128 CODE  
AREA



Marketed by:  
Pfizer, Madison, NJ 07940 USA  
© 2015 Pfizer Inc.  
Made in France  
For most recent product information, visit  
www.Nexium24HR.com  
Nexium is a registered trademark of  
AstraZeneca AB and is used under license.

128 CODE  
AREA

MICRO PRINT  
LOCATION

128 CODE = 052733

LOT & EXP AREA.  
DARK COLOR FOR  
LASER PRINTING.

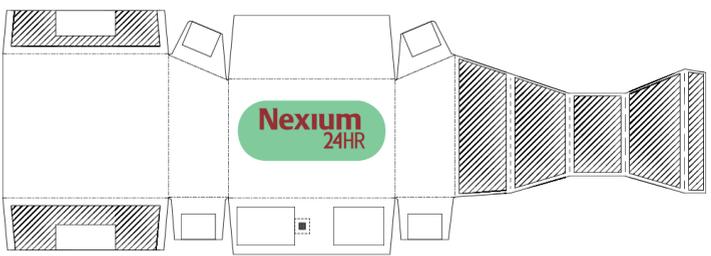
3/16" DATA MATRIX CODE WITH  
1/8" QUIET ZONE ON ALL SIDES  
DATA MATRIX CODE = 052733



128 CODE  
AREA

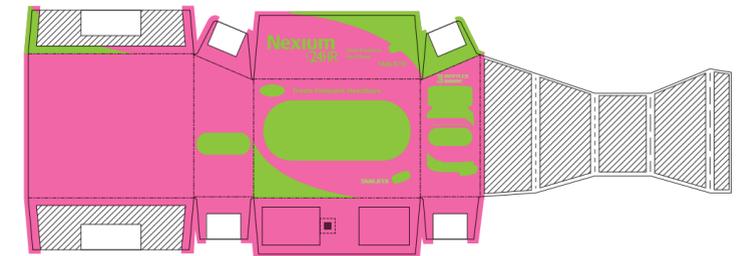
128 CODE = 052733

Emboss -  
Full size file on Emboss layer\*  
\* There are two levels of Embossing.



MICRO PRINT  
LOCATION

Gloss and Matte Varnish -  
Full size file on Varnish layer



**PRODUCTION**

(NOT COLOR ACCURATE)

Job Information	Color Legend
(b) (4)	

DRUG FACTS TEXT DEFINED	TYPE SIZE
• DRUG FACTS TITLE	9 pt
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• BARLINES, HAIRLINES	1.5 pt, .5 pt
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces

**NEW**

Treats Frequent Heartburn

**Nexium<sup>®</sup>**  
esomeprazole  
delayed-release tablets **24HR**  
20 mg/acid reducer

May take 1 to 4 days for full effect

**3 Pack**

**42 TABLETS**  
Three 14-day courses of treatment

REMOVE VARNISH IN THIS AREA ONLY

WHITE HOLDOUT QUIET AREA

DATA MATRIX CODE **052736**

REMOVE VARNISH  
WHITE HOLDOUT  
LOT/EXP

PA052736.F0004

3 05273 2451 43 5

**FPO**

Made in France  
© 2015, Pfizer, Inc.  
Marketed by: Pfizer, Madison, NJ 07940 USA  
Nexium is a registered trademark of AstraZeneca  
For most recent product information, visit  
www.Nexium24HR.com  
Ab and is used under license.

**Drug Facts**  
**Active ingredient (in each tablet)** Esomeprazole 20 mg (Each delayed-release tablet 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**  
• Do not use if you are allergic to esomeprazole  
• Do not use if you have:  
• chest pain or shoulder pain with shortness of breath, sweating, black stools  
• trouble or pain swallowing food, vomiting with blood, or bloody or black stools  
• heartburn with lightheadedness, sweating or dizziness  
• chest pain or shoulder, neck or shoulder, 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, digoxin or clozapine (blood-thinning medicines)  
• prescription antifungal or anti-yeast medicines  
• dexamethasone (steroid medicine)  
• diazepam (anxiety medicine)  
• tacrolimus or mycophenolate mofetil (immune system medicines)  
• 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  
• 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  
• 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 tablet with a glass of water before eating in the morning  
• Take every day for 14 days  
• Do not take more than 1 tablet a day  
• Swallow whole. Do not crush or chew tablets.  
• Do not use for more than 14 days unless directed by your doctor

**Repeated 14-Day Courses (if needed)**  
• You may repeat 14-day courses 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**  
• Children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.  
• Read the directions and warnings before use  
• Keep the card. It contains important information.

**Inactive ingredients**  
• 20 mg: aluminum lake, FD&C red no. 40 aluminum lake, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer, meta, microcrystalline cellulose, paraffin, polyethylene glycol, poly sorbate 80, sodium stearyl fumarate, sucrose, talc, titanium dioxide, triethyl citrate

**Questions or comments?**  
call toll-free, weekdays 9 AM to 5 PM EST at 1-866-226-1600

**Drug Facts (continued)**  
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.

**Keep Card for Complete Warnings and Important Information.**

**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.

**Do Not Use if seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing.**

**PRODUCTION** (NOT COLOR ACCURATE)

Job Information	Color Legend

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• 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



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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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KAREN M MAHONEY  
11/23/2015