



NDA 208025/S-005

SUPPLEMENT APPROVAL

Dexcel Pharma Technologies Ltd
U.S. Agent-ICON Clinical Research, LLC
Attention: Amy Kneifel, RAC
Director, Regulatory Affairs
79 TW Alexander Drive
4401 Research Commons Bldg., Suite 300
PO Box 14353
Durham, NC 27709

Dear Ms. Kneifel:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 17, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for lansoprazole delayed-release orally disintegrating tablet, 15 mg.

This “Changes Being Effected” (CBE-0) supplemental new drug application provides for the addition of a new warning to inform consumers to stop use and ask a doctor if they develop a rash or joint pain in accordance with the Agency’s CBE-0 Request Letter dated April 6, 2017.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the labeling listed below, submitted May 17, 2017. The final printed labeling must also be in the “Drug Facts” format (21 CFR 201.66), where applicable.

- 14-count inner carton
- 14-count carton
- 28-count carton
- 42-count carton
- 14-count carton with ‘Melts in your Mouth’ flag
- 28-count carton with ‘Melts in your Mouth’ flag
- 42-count carton with ‘Melts in your Mouth’ flag
- 14-count carton with ‘Orally Disintegrating Tablets’ flag

- 28-count carton with ‘Orally Disintegrating Tablets’ flag
- 42-count carton with ‘Orally Disintegrating Tablets’ flag
- 14-count carton with ‘Child-resistant’ flag
- 28-count carton with ‘Child-resistant’ flag
- 42-count carton with ‘Child-resistant’ flag
- 28-count carton with ‘Value 2 Pack’ flag
- 42-count carton with ‘Value 3 Pack’ flag
- 28-count carton with ‘Buy One 14 Count, Get One 14 Count Free!’ flag
- 28-count carton with ‘100% More Free! 14 Free Tablets!’ flag
- 28-count carton with ‘Bonus Size! 14 Tablets Free’ flag
- 28-count carton with ‘Bonus! + 14 Free’ flag
- 28-count carton with ‘Bonus! 14 Tablets FREE’ flag
- 28-count carton with ‘Bonus Size! 14 Free’ flag
- 42-count carton with ‘Bonus Pack: 28 + 14 Free’ flag
- 42-count carton with ‘Bonus Size! 14 Tablets Free’ flag
- 42-count carton with ‘Bonus! 14 Tablets FREE’ flag
- 42-count carton with ‘Bonus! + 14 Free’ flag
- 42-count carton with ‘Bonus Size! 14 Free’ flag
- Consumer Information Leaflet (front and back)

Remove the statement “New Dosage Form!” six months after introduction to the marketplace.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 208025/S-005.**” Approval of this submission by FDA is not required before the labeling is used.

As a reminder, if you are interested in marketing other package configurations in the future (e.g., individual containers containing greater than 14 tablets, total package sizes greater than 42-count), a prior approval supplement that includes data to demonstrate consumer comprehension of use is required.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:

Carton and Container Labeling

Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
14 Tablets

Batch No.
 EXP
 8U174 FA C4

CODE AREA

<p>Drug Facts (continued)</p> <p>Active ingredient (in each tablet) Lansoprazole 15mg, Acid reducer</p> <p>Purpose ■ treats frequent heartburn (occurs <i>2 or more</i> 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 lansoprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ liver disease ■ 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 chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ zidovudine (medication for HIV infection) ■ methoxazole (arthritis medicine)</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 get diarrhea ■ you develop a rash or joint pain</p>	<p>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 ■ 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 ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol</p> <p>Repeated 14-Day Course (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>Other information ■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p>
<p>Drug Facts (continued)</p> <p>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 ■ 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 ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol</p> <p>Repeated 14-Day Course (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>Other information ■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p>	<p>Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscollon, fumed silica, hydroxypropylcellulose, hypromellose, lactose monohydrate, mannitol, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.



KEEP THE CARTON AND PACKAGE INSERT.
 THEY CONTAIN IMPORTANT INFORMATION.

Safety Feature –
 Do not use if printed tablet blister unit is open or torn.

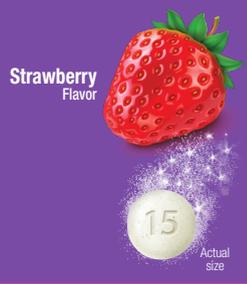
NDC 64239-181-01

Compare to the active ingredient in Prevacid® 24 HR*

New Dosage Form!

24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg
Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn



14 TABLETS ONE 14-DAY COURSE OF TREATMENT

Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel
 Made in Israel

Drug Facts (continued)
Questions or comments? 1-800-719-9260, weekdays 7:30 AM to 5:00 PM EST

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

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
14 Tablets**

Batch No.
EXP
8U174 FA C4-T

CODE AREA

<p>Drug Facts (continued)</p> <p>Active ingredient (in each tablet) Lansoprazole 15mg Acid reducer</p> <p>Purpose ■ 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 ■ Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ Ask a doctor before use if you have ■ liver disease ■ 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 wheezing, particularly with heartburn ■ stomach pain ■ nausea or vomiting</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ atazanavir (medicine for HIV infection) ■ methoxsalol (artthritis medicine)</p> <p>Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain</p>	<p>Directions ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ adults 18 years of age and older ■ 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 ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue, tablet disintegrates, with or without water. ■ take every day for 14 days</p> <p>Repeated 14-Day Course (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.</p> <p>Other information ■ read the directions, warnings and package insert before use ■ keep the carton and package insert. They contain important information. ■ protect product from moisture ■ store at 20-25°C (68-77°F) ■ copovidone, croscopolone, fumed, hypromellose, hypromellose phthalate, polyosorbate 80, polyvinyl glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucrose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>
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*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24HR.



KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

Safety Feature –
Do not use if printed tablet blister unit is open or torn.

New Dosage Form!

**24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg**

Acid Reducer

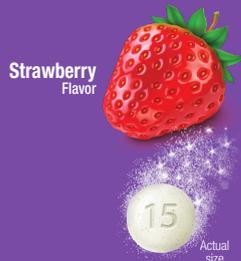
Melts in your mouth
Dissolves without water

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

14 TABLETS ONE 14-DAY COURSE OF TREATMENT

Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-01



Made in Israel
Manufactured by:
Dexel Pharma Technologies Ltd
10 Hakdima Street, Yokneam 2069200, Israel

Drug Facts (continued)
Questions or comments? 1-800-719-9260
weekdays 7:30 AM to 5:00 PM EST

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

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
28 Tablets**

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.
Dexcel Pharma Technologies Ltd
10 Hakdima Street, Yokneam 2069200, Israel
Manufactured by:
Made in Israel

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

Drug Facts (continued)
Inactive ingredients: ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, maize maltoedextrin, mannitol, microcrystalline cellulose, polyosorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Drug Facts
Active ingredient (in each tablet) Lansoprazole 15mg.....Acid reducer
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 lansoprazole
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
■ liver disease
■ had heartburn over 3 months. This may be a sign of a more serious condition
■ heartburn with **hightheadness, 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

Ask a doctor or pharmacist before use if you are taking
■ warfarin (blood-thinning medicine) or anti-yeast medicines
■ digoxin (heart medicine)
■ theophylline (asthma medicine)
■ tacrolimus or mycophenolate mofetil (immune system medicines)
■ azacitidine (medicine for HIV infection)
■ methotrexate (arthritis medicine)

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
■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
■ take 1 tablet before eating in the morning

14-Day Course of Treatment
■ take 1 tablet before eating in the morning
■ do not crush or chew tablets
The tablets can also be swallowed whole with water.
■ place the tablet on tongue; tablet disintegrates, with or without water.
■ take every day for 14 days
■ do not take more than 1 tablet a day
■ do not use for more than 14 days unless directed by your doctor.
■ do not take this medicine with alcohol

Repeated 14-Day Course (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

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, warnings and package insert before use
■ keep the carton and package insert. They contain important information.
■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity
■ protect product from moisture

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 get diarrhea ■ you develop a rash or joint pain
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).

CODE AREA

Batch No.
EXP
8U130 FA C4-T



Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Safety Feature – Do not use if printed
tablet blister unit is open or torn.

KEEP THE CARTON AND PACKAGE INSERT.
THEY CONTAIN IMPORTANT INFORMATION.

Compare to the active ingredient
in Prevacid® 24 HR*

NDC 64239-181-02

New Dosage Form!
24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg
Acid Reducer

Melts in your mouth
Dissolves without water

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Strawberry Flavor




STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued)
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
14 Tablets**

Batch No.
EXP
8U174 FA C4-V

CODE AREA

<p>Drug Facts (continued)</p> <p>Active ingredient (in each tablet) Lansoprazole 15mg,Acid reducer</p> <p>PurposeAcid reducer</p>	<p>Use</p> <ul style="list-style-type: none"> ■ Treats frequent heartburn (occurs 2 or more days a week) 1 to 4 days for full effect ■ Not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect <p>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Do not use if you have trouble or pain swallowing food, vomiting with blood, or 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</p> <ul style="list-style-type: none"> ■ liver disease ■ 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 shoulder; or lightheadedness <p>Chest pain</p> <ul style="list-style-type: none"> ■ frequent wheezing, particularly with heartburn ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ atazanavir (medicine for HIV infection) ■ methotrexate (arthritis medicine) <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you develop a rash or joint pain ■ you get diarrhea
<p>Directions</p> <ul style="list-style-type: none"> ■ 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>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol <p>Repeated 14-Day Course (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 <p>Other Information</p> <ul style="list-style-type: none"> ■ 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, warnings and package insert before use ■ keep the carton and package insert. They contain important information. ■ store at 20-25°C (68-77°F). ■ keep product out of high heat and humidity ■ protect product from moisture <p>Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolvidone, flavor, hydroxypropylmethylcellulose, hydroxypropylcellulose, hypromellose, hypromellose phthalate, polypropylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>	<p>Drug Facts (continued)</p> <p>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>

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.



KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

Safety Feature –
Do not use if printed tablet blister unit is open or torn.

NDC 64239-181-01

Compare to the active ingredient in Prevacid® 24 HR*

New Dosage Form!

24 Hour Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg

Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

14 TABLETS

ONE 14-DAY COURSE OF TREATMENT

Strawberry
Flavor



Orally
Disintegrating
Tablets



Actual size

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

Drug Facts (continued)
Questions or comments? 1-800-779-9260:
weekdays 7:30 AM to 5:00 PM EST

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

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
42 Tablets**

This product is not manufactured or distributed by Novartis Consumer Health, Inc.; distributor of Prevacid® 24 HR.
 Manufactured by:
 Cexcel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel
 Made in Israel

Questions or comments? 1-800-719-9260, weekdays 7:30 AM to 5:00 PM EST

Drug Facts (continued)
Inactive ingredients: ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, mazel maldodecyltri, mannitol, magnesium, microcrystalline cellulose, polyborate B, polyborate B, polyethylene glycol, polypropylene glycol, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Drug Facts
Active ingredient (in each tablet)
 Lansoprazole 15mg.....Acid reducer
Purpose
 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 have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
 ■ liver disease
 ■ head 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

Ask a doctor or pharmacist before use if you are taking
 ■ warfarin (blood-thinning medicine)
 ■ prescription antifungal or anti-yeast medicines
 ■ digoxin (heart medicine)
 ■ theophylline (asthma medicine)
 ■ tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ azaravir (medicine for HIV infection)
 ■ methotrexate (arthritis medicine)

Other information
 ■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.
 ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor
 ■ you may repeat a 14-day course every 4 months
Repeated 14-Day Course (if needed)
 ■ do not take this medicine with alcohol
 ■ do not use for more than 14 days unless directed by your doctor
 ■ do not take more than 1 tablet a day
 ■ take every day for 14 days
 ■ take every day for 14 days
 ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
 ■ do not crush or chew tablets
 ■ take 1 tablet before eating in the morning
14-Day Course of Treatment
 ■ 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

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

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

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
 ■ 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
 ■ take 1 tablet before eating in the morning
Do not crush or chew tablets
 ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
 ■ do not take more than 1 tablet a day
 ■ take every day for 14 days
 ■ do not use for more than 14 days unless directed by your doctor
 ■ do not take this medicine with alcohol
Repeated 14-Day Course (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.

CODE AREA

Batch No.
 EXP
 8U155 FA C4-V

Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Safety Feature – Do not use if printed tablet blister unit is open or torn.

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

NDC 64239-181-03

*Compare to the active ingredient in Prevacid® 24 HR**

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg

Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

42 TABLETS THREE 14-DAY COURSES OF TREATMENT

Strawberry Flavor 

Orally Disintegrating Tablets  Actual size

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
14 Tablets**

Batch No.
EXP
8U174 FA C4-J

CODE AREA

<p>Drug Facts (continued)</p> <p>Active Ingredient (in each tablet) Lansoprazole 15mg;acid reducer</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 lansoprazole blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.</p> <p>Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition.</p> <p>Ask a doctor before use if you have ■ liver disease ■ 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</p> <p>requent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ atazanavir (medicine for HIV infection) ■ methotrexate (arthritis medicine)</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 develop a rash or joint pain ■ you get diarrhea</p>	<p>Purpose Acid reducer</p>
<p>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 ■ 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 ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.</p> <p>Take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol</p> <p>Repeated 14-Day Course (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 before use; heartburn in children may sometimes be caused by a serious condition.</p> <p>Other Information ■ read the directions, warnings and package insert before use ■ keep the carton and package insert. They contain important information. ■ protect product from moisture ■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity ■ copovidone, croscopolidone, flavor, hypromellose, hydroxyethylcellulose, maize maltoedextrin, methylol, mannitol, meglumine, microcrystalline cellulose, polyisobutyl glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>	<p>Drug Facts (continued)</p> <p>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>

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.



KEEP THE CARTON AND PACKAGE INSERT.
THEY CONTAIN IMPORTANT INFORMATION.

Safety Feature –
Do not use if printed tablet blister unit is open or torn.

Child-resistant

Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-01

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg

Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

Strawberry
Flavor



14 TABLETS

ONE 14-DAY COURSE
OF TREATMENT

Manufactured by:
Cexel Pharma Technologies Ltd
10 Hakdima Street, Yokneam 2069200, Israel
Made in Israel

Drug Facts (continued)

Questions or comments? 1-800-719-9260.
weekdays 7:30 AM to 5:00 PM EST

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**

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
28 Tablets**

This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.
 Manufactured by:
 Cexcel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, mize maldextrin, maltitol, mannitol, microcrystalline cellulose, polyborate 80, propylene glycol, polyvinylpyrrolidone, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

Drug Facts
Active ingredient (in each tablet) Lansoprazole 15mg; Acid reducer

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 lansoprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have
 ■ liver disease
 ■ 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

Ask a doctor or pharmacist before use if you are taking
 ■ warfarin (blood-thinning medicine)
 ■ prescription antifungal or anti-yeast medicines
 ■ digoxin (heart medicine)
 ■ theophylline (asthma medicine)
 ■ tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ zidovudine (medicine for HIV infection)
 ■ methotrexate (arthritis medicine)

Other information
 ■ read the directions, warnings and package insert before use
 ■ keep the carton and package insert. They contain important information.
 ■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity
 ■ protect product from moisture

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
 ■ relief of symptoms within 24 hours

14-Day Course of Treatment
 ■ take 1 tablet before eating in the morning
 ■ do not crush or chew tablets
 ■ place the tablet on tongue, tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
 ■ take every day for 14 days
 ■ do not take more than 1 tablet a day
 ■ do not use for more than 14 days unless directed by your doctor
 ■ do not take this medicine with alcohol

Repeated 14-Day Course (if needed)
 ■ you may repeat 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.

Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

CODE AREA

Batch No. 8U130 FA C4-J
 EXP



Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Safety Feature – Do not use if printed tablet blister unit is open or torn.

KEEP THE CARTON AND PACKAGE INSERT.
 THEY CONTAIN IMPORTANT INFORMATION.

Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-02

Child-resistant

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg

Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Strawberry Flavor 

 Actual size

STANDARD FORMAT

TYPE SIZES:
 TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
 TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued) 8 pt Helvetica Neue 57 Condensed
 HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
 SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
 TEXT: 6 pt Helvetica Neue 57 Condensed
 LEADING: 6.5 pt
 BULLETS: 5 pt Square
 TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
 HEAVY LINES: 1.5 pt
 HAIRLINES: 0.5 pt

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
42 Tablets**

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.
Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel
Manufactured by:
Made in Israel

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, favaic, hypromellose, hypromellose phthalate, maize maltoedextrin, maltitol, mannitol, microcrystalline cellulose, polyosorbate 80, propylene glycol, silicon dioxide, sodium lauryl sulfate, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Drug Facts (continued)

Warnings Do not use if you are allergic to lansoprazole. Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

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.

Active ingredient (in each tablet) Lansoprazole 15mg; Acid reducer

Purpose 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. You develop a rash or joint pain.

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. 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 Take 1 tablet before eating in the morning. Do not crush or chew tablets. Place the tablet on tongue, tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. Take every day for 14 days. Do not take more than 1 tablet a day. Do not use for more than 14 days unless directed by your doctor. Do not take this medicine with alcohol.

Repeated 14-Day Course (if needed) You may repeat a 14-day course every 4 months unless directed by a doctor. Do not take for more than 14 days or more often than every 4 months.

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, warnings and package insert before use. Keep the carton and package insert. They contain important information. Store at 20-25°C (68-77°F). Keep product out of high heat and humidity. Protect product from moisture.

CODE AREA

Batch No. EXP 8U155 FA C4-J

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg



Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Safety Feature – Do not use if printed
tablet blister unit is open or torn.

KEEP THE CARTON AND PACKAGE INSERT.
THEY CONTAIN IMPORTANT INFORMATION.

Compare to the active ingredient
in Prevacid® 24 HR*

NDC 64239-181-03

Child-resistant

New Dosage Form!
24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

42 TABLETS THREE 14-DAY COURSES OF TREATMENT

Strawberry Flavor 

 Actual size

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
28 Tablets

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Drug Facts (continued)
Inactive ingredients (continued)
 ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, maize milledextrin, mannitol, microcrystalline cellulose, polyvinylpyrrolidone, polyvinylpyrrolidone K90, propylene glycol, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakdama Street, Yokneam 2069200, Israel
 Made in Israel

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

Drug Facts
Active ingredient (in each tablet)
 Lansoprazole 15mg.....Acid reducer

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 lansoprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or 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
 ■ liver disease
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
 ■ 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 (blood-thinning medicine)
 ■ prescription antifungal or anti-yeast medicines
 ■ digoxin (heart medicine)
 ■ theophylline (asthma medicine)
 ■ tacrolimus or mycophenolate mofetil (immune system medicines)
 ■ atazanavir (medicine for HIV infection)
 ■ methotrexate (arthritis medicine)

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
 ■ 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
 ■ take 1 tablet before eating in the morning
 ■ do not crush or chew tablets
 ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
 ■ take every day for 14 days
 ■ do not use for more than 14 days unless directed by your doctor
 ■ do not take this medicine with alcohol

Repeated 14-Day Course (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

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, warnings and package insert before use
 ■ keep the carton and package insert. They contain important information.
 ■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity

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

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).

Batch No. 8U130 FA C4-A
EXP
CODE AREA



Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Safety Feature – Do not use if printed tablet blister unit is open or torn.

KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.

Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-02

Value 2 Pack

New Dosage Form!
24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg
Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Strawberry Flavor



Actual size

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued)
8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
28 Tablets**

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

DeceL Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel
Manufactured by:
Made in Israel

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

Inactive Ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, maize malodextrin, mannitol, magnesium, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate



Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

<p>Drug Facts (continued)</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 ■ you develop a rash or joint pain</p> <p>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</p> <p>■ 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</p> <p>■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.</p> <p>■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol</p> <p>Repeated 14-Day Course (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 before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other Information</p> <p>■ read the directions, warnings and package insert before use ■ keep the carton and package insert. They contain important information. ■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity ■ protect product from moisture</p>	<p>Drug Facts</p> <p>Use</p> <p>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>■ frequent heartburn (occurs 2 or more days a week)</p> <p>■ Lansoprazole 15mg.....Acid reducer</p> <p>Active ingredient (in each tablet)</p> <p>Purpose</p> <p>Warnings</p> <p>Do not use if you have trouble or pain swallowing food, vomiting with blood, or 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</p> <p>■ liver disease ■ 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</p> <p>Ask a doctor or pharmacist before use if you are taking</p> <p>■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ atazanavir (medicine for HIV infection) ■ methotrexate (arthritis medicine)</p>
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CODE AREA

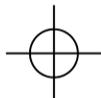
Batch No. EXP 8U130 FA C4-L



Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

**Safety Feature – Do not use if printed
tablet blister unit is open or torn.**

KEEP THE CARTON AND PACKAGE INSERT.
THEY CONTAIN IMPORTANT INFORMATION.



**100% More Free!
14 Free Tablets!**

Compare to the active ingredient
in Prevacid® 24 HR*

NDC 64239-181-02

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg

Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

28 TABLETS

TWO 14-DAY COURSES
OF TREATMENT

**Strawberry
Flavor**

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique
(continued) 8 pt Helvetica Neue 57 Condensed
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
28 Tablets**

**Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg**

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, maize maltoedextrin, mannitol, magnesium, microcrystalline cellulose, polyborate 80, polyethylene glycol, propylene glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate
Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST
 Made in Israel
 Manufactured by:
 Decel Pharma Technologies Ltd
 10 Hakidma Street, Yokneam 2069200, Israel
 *This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

Drug Facts
Active ingredient (in each tablet) Lansoprazole 15mg.....Acid reducer
Purpose ■ 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 have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. ■ **Ask a doctor before use if you have** liver disease ■ head 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
Ask a doctor or pharmacist before use if you are taking ■ warfarin (blood-thinning medicine) ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ alazanavir (medicine for HIV infection) ■ methotrexate (arthritis medicine)
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 ■ 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** ■ take 1 tablet before eating in the morning ■ **do not crush or chew tablets** ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol
Repeated 14-Day Course (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, warnings and package insert before use ■ keep the carton and package insert. They contain important information. ■ store at 20-25°C (68-77°F). ■ keep product out of high heat and humidity ■ protect product from moisture
Drug Facts (continued) ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you develop a rash or joint pain ■ you get diarrhea ■ you need to take more than 1 course of treatment every 4 months
Stop use and ask a doctor if ■ you are pregnant or breastfeeding, 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).
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
14-Day Course of treatment ■ take 1 tablet before eating in the morning ■ **do not crush or chew tablets** ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol
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Other information ■ read the directions, warnings and package insert before use ■ keep the carton and package insert. They contain important information. ■ store at 20-25°C (68-77°F). ■ keep product out of high heat and humidity ■ protect product from moisture

CODE AREA

8U130 FA C4-P

Batch No.

EXP



**Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg**

Safety Feature – Do not use if printed tablet blister unit is open or torn.

KEEP THE CARTON AND PACKAGE INSERT.
THEY CONTAIN IMPORTANT INFORMATION.

Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-02

Bonus Size! 14 Free

New Dosage Form!
24 Hour
Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg
Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Strawberry Flavor

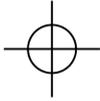


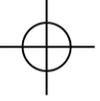
Actual size

STANDARD FORMAT

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HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
42 Tablets**


CODE AREA
 Batch No. _____
 EXP _____
 8U155 FA C4-M


Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Drug Facts (continued)

Warnings do not use if you are allergic to lansoprazole
 Allergy alert: do not use if you are allergic to lansoprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have
 liver disease
 head or neck pain
 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
 Ask a doctor or pharmacist before use if you are taking
 warfarin (blood-thinning medicine)
 prescription antifungal or anti-yeast medicines
 digoxin (heart medicine)
 theophylline (asthma medicine)
 tacrolimus or mycophenolate mofetil (immune system medicines)
 atazanavir (medicine for HIV infection)
 methotrexate (arthritis medicine)

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

Active ingredient (in each tablet)
 Lansoprazole 15mg.....Acid reducer

Purpose
 Stop use and ask a doctor if 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
 you develop a rash or joint pain

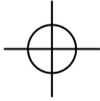
Directions
 adults 18 years of age and older
 this product is to be used once a day (every 24 hours), every day for 14 days
 it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
 14-Day Course of Treatment
 take 1 tablet before eating in the morning
 do not crush or chew tablets
 place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
 take every day for 14 days
 do not take more than 1 tablet a day
 do not use for more than 14 days unless directed by your doctor
 do not take this medicine with alcohol
 Repeated 14-Day Course (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.

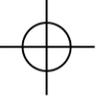
Other information
 read the directions, warnings and package insert before use
 keep the carton and package insert. They contain important information.
 store at 20-25°C (68-77°F) ■ Keep product out of high heat and humidity
 protect product from moisture

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, fava, hypromellose, hypromellose phthalate, mazel malodextrin, mannitol, magnesium, microcrystalline cellulose, polyborate 80, propylene glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260, weekdays 7:30 AM to 5:00 PM EST

Made in Israel
 Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel
 *This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.


CODE AREA
 Batch No. _____
 EXP _____
 8U155 FA C4-M


Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Drug Facts (continued)

Warnings do not use if you are allergic to lansoprazole
 Allergy alert: do not use if you are allergic to lansoprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have
 liver disease
 head or neck pain
 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
 Ask a doctor or pharmacist before use if you are taking
 warfarin (blood-thinning medicine)
 prescription antifungal or anti-yeast medicines
 digoxin (heart medicine)
 theophylline (asthma medicine)
 tacrolimus or mycophenolate mofetil (immune system medicines)
 atazanavir (medicine for HIV infection)
 methotrexate (arthritis medicine)

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

Active ingredient (in each tablet)
 Lansoprazole 15mg.....Acid reducer

Purpose
 Stop use and ask a doctor if 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
 you develop a rash or joint pain

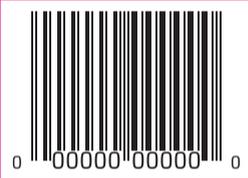
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 do not use for more than 14 days unless directed by your doctor
 do not take this medicine with alcohol
 Repeated 14-Day Course (if needed)
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 children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

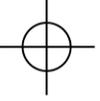
Other information
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 store at 20-25°C (68-77°F) ■ Keep product out of high heat and humidity
 protect product from moisture

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, fava, hypromellose, hypromellose phthalate, mazel malodextrin, mannitol, magnesium, microcrystalline cellulose, polyborate 80, propylene glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260, weekdays 7:30 AM to 5:00 PM EST

Made in Israel
 Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel
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CODE AREA
 Batch No. _____
 EXP _____
 8U155 FA C4-M


Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Drug Facts (continued)

Warnings do not use if you are allergic to lansoprazole
 Allergy alert: do not use if you are allergic to lansoprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have
 liver disease
 head or neck pain
 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
 Ask a doctor or pharmacist before use if you are taking
 warfarin (blood-thinning medicine)
 prescription antifungal or anti-yeast medicines
 digoxin (heart medicine)
 theophylline (asthma medicine)
 tacrolimus or mycophenolate mofetil (immune system medicines)
 atazanavir (medicine for HIV infection)
 methotrexate (arthritis medicine)

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

Active ingredient (in each tablet)
 Lansoprazole 15mg.....Acid reducer

Purpose
 Stop use and ask a doctor if 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
 you develop a rash or joint pain

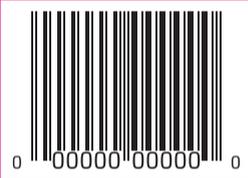
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 take every day for 14 days
 do not take more than 1 tablet a day
 do not use for more than 14 days unless directed by your doctor
 do not take this medicine with alcohol
 Repeated 14-Day Course (if needed)
 you may repeat a 14-day course every 4 months
 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.

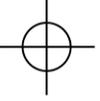
Other information
 read the directions, warnings and package insert before use
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 store at 20-25°C (68-77°F) ■ Keep product out of high heat and humidity
 protect product from moisture

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, fava, hypromellose, hypromellose phthalate, mazel malodextrin, mannitol, magnesium, microcrystalline cellulose, polyborate 80, propylene glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260, weekdays 7:30 AM to 5:00 PM EST

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 Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel
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CODE AREA
 Batch No. _____
 EXP _____
 8U155 FA C4-M


Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Drug Facts (continued)

Warnings do not use if you are allergic to lansoprazole
 Allergy alert: do not use if you are allergic to lansoprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have
 liver disease
 head or neck pain
 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
 Ask a doctor or pharmacist before use if you are taking
 warfarin (blood-thinning medicine)
 prescription antifungal or anti-yeast medicines
 digoxin (heart medicine)
 theophylline (asthma medicine)
 tacrolimus or mycophenolate mofetil (immune system medicines)
 atazanavir (medicine for HIV infection)
 methotrexate (arthritis medicine)

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

Active ingredient (in each tablet)
 Lansoprazole 15mg.....Acid reducer

Purpose
 Stop use and ask a doctor if 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
 you develop a rash or joint pain

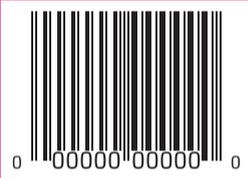
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 do not use for more than 14 days unless directed by your doctor
 do not take this medicine with alcohol
 Repeated 14-Day Course (if needed)
 you may repeat a 14-day course every 4 months
 do not take for more than 14 days or more often than every 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.

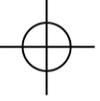
Other information
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 keep the carton and package insert. They contain important information.
 store at 20-25°C (68-77°F) ■ Keep product out of high heat and humidity
 protect product from moisture

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, fava, hypromellose, hypromellose phthalate, mazel malodextrin, mannitol, magnesium, microcrystalline cellulose, polyborate 80, propylene glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260, weekdays 7:30 AM to 5:00 PM EST

Made in Israel
 Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel
 *This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.


CODE AREA
 Batch No. _____
 EXP _____
 8U155 FA C4-M


Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Drug Facts (continued)

Warnings do not use if you are allergic to lansoprazole
 Allergy alert: do not use if you are allergic to lansoprazole
 Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
 Ask a doctor before use if you have
 liver disease
 head or neck pain
 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
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 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 (blood-thinning medicine)
 prescription antifungal or anti-yeast medicines
 digoxin (heart medicine)
 theophylline (asthma medicine)
 tacrolimus or mycophenolate mofetil (immune system medicines)
 atazanavir (medicine for HIV infection)
 methotrexate (arthritis medicine)

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

Active ingredient (in each tablet)
 Lansoprazole 15mg.....Acid reducer

Purpose
 Stop use and ask a doctor if 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
 you develop a rash or joint pain

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
 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
 take 1 tablet before eating in the morning
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 place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
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 do not take more than 1 tablet a day
 do not use for more than 14 days unless directed by your doctor
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 Repeated 14-Day Course (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, warnings and package insert before use
 keep the carton and package insert. They contain important information.
 store at 20-25°C (68-77°F) ■ Keep product out of high heat and humidity
 protect product from moisture

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, fava, hypromellose, hypromellose phthalate, mazel malodextrin, mannitol, magnesium, microcrystalline cellulose, polyborate 80, propylene glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments? 1-800-719-9260, weekdays 7:30 AM to 5:00 PM EST

Made in Israel
 Manufactured by:
 Dexel Pharma Technologies Ltd
 10 Hakdima Street, Yokneam 2069200, Israel
 *This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued)
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
42 Tablets**

*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel
Manufactured by:
Made in Israel

Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, fumed silica, hydroxypropyl methylcellulose, hypromellose phthalate, maize maltoedextrin, mannitol, microcrystalline cellulose, polyborate 80, polypropylene glycol, polyvinylpyrrolidone, sodium hydroxide, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide, triethyl citrate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

CODE AREA

8U155 FA C4-R

Batch No. _____
EXP _____

Drug Facts
Active ingredient (in each tablet) Lansoprazole 15mg.....Acid reducer
Purpose 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 ■ you develop a rash or joint pain
 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).

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 ■ 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
 ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol

Repeated 14-Day Course (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

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, warnings and package insert before use ■ keep the carton and package insert. They contain important information. ■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity ■ protect product from moisture

Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
 ■ liver disease ■ 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

Ask a doctor or pharmacist before use if you are taking
 ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ atazanavir (medicine for HIV infection) ■ methotrexate (arthritis medicine)

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

Allergy alert: do not use if you are allergic to lansoprazole

Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

CODE AREA

8U155 FA C4-R

Batch No. _____
EXP _____

Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Safety Feature – Do not use if printed tablet blister unit is open or torn.

KEEP THE CARTON AND PACKAGE INSERT.
 THEY CONTAIN IMPORTANT INFORMATION.

CODE AREA

8U155 FA C4-R

Batch No. _____
EXP _____

Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-03

Bonus! + 14 Free

New Dosage Form!
24 Hour
Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg
 Acid Reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- Clinically Proven To Treat Frequent Heartburn

42 TABLETS THREE 14-DAY COURSES OF TREATMENT

Strawberry Flavor



15 Actual size

STANDARD FORMAT

TYPE SIZES:
TITLE: 9 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique (continued)
HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6.5 pt
BULLETS: 5 pt Square
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

**Final Printed Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
42 Tablets**



*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.
 10 Hakidma Street, Yokneam 2069200, Israel
 Manufactured by:
 Dexel Pharma Technologies Ltd
 Made in Israel

Drug Facts (continued)
Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, copovidone, flavor, hypromellose, hypromellose phthalate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate
Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST

CODE AREA

Batch No.
 EXP
 8U155 FA C4-P

Drug Facts

Active ingredient (in each tablet) Lansoprazole 15mg.....Acid reducer

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

Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diaxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

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
- 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

- take 1 tablet before eating in the morning
- **do not crush or chew tablets**
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not take this medicine with alcohol

Repeated 14-Day Course (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**

Other information

- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.
- protect product from moisture
- store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity
- read the directions, warnings and package insert before use
- keep the carton and package insert. They contain important information.

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

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).

Drug Facts (continued)

Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg



Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg

Safety Feature – Do not use if printed tablet blister unit is open or torn.

KEEP THE CARTON AND PACKAGE INSERT.
 THEY CONTAIN IMPORTANT INFORMATION.



Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-03

Bonus Size! 14 Free

New Dosage Form!
24 Hour
Lansoprazole
 Delayed Release
 Orally Disintegrating Tablets 15 mg
 Acid Reducer

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Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg

acid reducer

- May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

Please read the entire package insert before taking
Lansoprazole Delayed Release Orally Disintegrating Tablets.
Save for future reference.

How Lansoprazole delayed release orally disintegrating tablets Treats Your Frequent Heartburn

Lansoprazole delayed release orally disintegrating tablets stops acid production at the source—the pumps that release acid into the stomach. Lansoprazole delayed release orally disintegrating tablets is taken once a day (every 24 hours) every day for 14 days.

What You Can Expect When Taking Lansoprazole delayed release orally disintegrating tablets

Frequent heartburn can occur anytime during the 24-hour period (day or night). Take Lansoprazole delayed release orally disintegrating tablets in the morning before eating. Lansoprazole is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take Lansoprazole delayed release orally disintegrating tablets every day for 14 days to treat your frequent heartburn.

Who Should Take Lansoprazole delayed release orally disintegrating tablets

Adults (18 years and older) with frequent heartburn—when you have heartburn 2 or more days a week.

Who Should NOT Take Lansoprazole delayed release orally disintegrating tablets

People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to Take Lansoprazole delayed release orally disintegrating tablets 14-DAY Course of treatment

- take 1 tablet before eating in the morning.
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor.
- do not take this medicine with alcohol

When to Take Lansoprazole delayed release orally disintegrating tablets Again

You may repeat a 14-day course of therapy every 4 months.

When to Talk to Your Doctor

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



Warnings and When to Ask Your Doctor

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

Do not use

- If you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- liver disease
- 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

Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- digoxin (heart medicine)
- theophylline (asthma medicine)
- tacrolimus or mycophenolate mofetil (immune system medicines)
- atazanavir (medicine 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
- you develop a rash or joint pain

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).

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.

Clinical studies prove that lansoprazole effectively treats frequent heartburn

In three clinical studies, lansoprazole was shown to be significantly better than placebo in treating frequent heartburn.

How Lansoprazole delayed release orally disintegrating tablets is Sold

This medicine is available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes 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 the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments About Lansoprazole delayed release orally disintegrating tablets

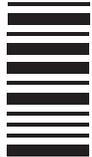
Call 1-800-719-9260

weekdays 7:30 AM to 5:00 PM EST

Made in Israel

Manufactured by:
Dexcel Pharma Technologies Ltd.,
10 Hakidma St. Yokneam 2069200, Israel

: 80100 00 J1
V_1362



A | B | C | D | E | F | G | H

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

/s/

VALERIE S PRATT
11/15/2017