This label may not be the latest approved by FDA.
For current labeling information, please visit https://www.fda.gov/drugsatfda

Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
14 Tablets

14.5 | 155.96 | 14.5

222.25 | 89 | 15.5 | 89

CODE AREA

Batch No.
EXP
: 8U174 00 CV1

Drug Facts

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

Use
- frequent heartburn (occurs 2 or more days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days to 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
- frequent **chest pain**
- frequent wheezing, part of asthma 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 (immunosystem 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 it sprout br more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

Inactive ingredients ascorbic acid, cellulose, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

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
- 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 Use (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 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

Inactive ingredients ascorbic acid, cellulose, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Drug Facts (continued)

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

Made in Israel

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

NOT FOR RESALE

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 64239-181-07

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 Strawberry Flavor
ONE 14-DAY COURSE OF TREATMENT

15
Actual size

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

7-6-16

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Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
14 Tablets

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

7-6-16

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Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg
28 Tablets

CODE AREA

Batch No.

EXP

: 8U130 FA C1

LANSOPRAZOLE
DELAYED RELEASE ORALLY
DISINTEGRATING TABLETS 15 mg

Drug Facts

Active ingredient (in each tablet)	Purpose
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 blood 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)
- bacrolimus or mycophenolate mofetil (immune system medicines)
- efavirenz (medicine for HIV infection)
- nelfinavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

Drug Facts (continued)

Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltodextin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucrose, 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:
Dexcel Pharma Technologies Ltd.
10 Hakidma St. Yokneam 2059200, Israel

Made in Israel

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

Drug Facts (continued)

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (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
- 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

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 64239-181-02

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

New Dosage Form!

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 Strawberry Flavor
TWO 14-DAY COURSES OF TREATMENT

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) 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

7-6-16

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For current labeling information, please visit https://www.fda.gov/drugsatfda

Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
42 Tablets

CODE AREA

Batch No.

EXP

: 8U155 FA C1

LANSOPRAZOLE
DELAYED RELEASE ORALLY
DISINTEGRATING TABLETS 15 mg

Drug Facts (continued)

Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucrose, 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:
Dexcel Pharma Technologies Ltd.
10 Hakidma St. 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)	Purpose
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
- **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 (immune system medicines)
- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

Drug Facts (continued)

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (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**
- 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

0 00000 00000 0

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

New Dosage Form!

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 Strawberry Flavor
THREE 14-DAY COURSES OF TREATMENT

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) 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

7-6-16