

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**208025Orig1s000**

**LABELING**

Proposed Draft Labeling  
 NDA 208025  
 Lansoprazole Delayed Release Orally  
 Disintegrating Tablets, 15 mg  
 Blister of 7 tablets

Place tablet on tongue; tablet disintegrates, with or without water. Do not crush or chew tablets. One 14-day course of treatment. Take 1 tablet every day for 14 days. Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

<p>6.5 pt Helvetica Black Cond.</p> <p>5 pt Helvetica Bold Cond.</p> <p>6 pt Helvetica Bold Cond.</p> <p>6 pt Helvetica Medium</p>	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer  <b>Push tablet through foil</b>          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam 2069200,          Israel</p>	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer  <b>Push tablet through foil</b>          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam 2069200,          Israel</p>
	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer  <b>Push tablet through foil</b>          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam 2069200,          Israel</p>	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer  <b>Push tablet through foil</b>          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam 2069200,          Israel</p>
	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer  <b>Push tablet through foil</b>          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam 2069200,          Israel</p>	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer  <b>Push tablet through foil</b>          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam 2069200,          Israel</p>

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

<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer</p> <p>Push tablet through foil          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam          2069200, Israel</p>	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer</p> <p>Push tablet through foil          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam          2069200, Israel</p>	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer</p> <p>Push tablet through foil          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam          2069200, Israel</p>
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<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer</p> <p>Push tablet through foil          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam          2069200, Israel</p>	<p>Place tablet on tongue; tablet          disintegrates, with or without water.          Do not chew or crush tablets.          One 14-day course of treatment.          Do not take for more than 14 days          or more often than every 4 months          unless directed by a doctor.</p>	<p><b>Lansoprazole</b>  <b>Delayed Release Orally</b>  <b>Disintegrating Tablets 15 mg</b>          acid reducer</p> <p>Push tablet through foil          Dexcel Pharma Technologies Ltd.          10 Hakidma St. Yokneam          2069200, Israel</p>
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5.5 pt Helvetica Black Cond. —  
 4.5 pt Helvetica Bold Cond. —  
 5 pt Helvetica Bold Cond. —  
 5 pt Helvetica Medium —

AF Dimension 100mm x 80.3 mm

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

A	B	C	D	E	F	G	H
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**15**

Actual size

**14 TABLETS**

Strawberry Flavor

ONE 14-DAY COURSE OF TREATMENT

0000000000

**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

**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.

**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 mofetil (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

**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, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

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

Batch No  
 EXP

0000000000

D-55

1-800-719-9260

**MODIFIED FORMAT**

**TYPE SIZES:**  
 TITLE: 9 pt Helvetica Bold Cond. Oblique  
 TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
 (continued) 7.5 pt Helvetica Medium Cond.  
 HEADINGS: 8 pt Helvetica Bold Cond. Oblique  
 SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique  
 TEXT: 6 pt Helvetica Medium Cond.  
 LEADING: 6.5 pt  
 BULLETS: 5 pt Square with 2 M'S spacing between statements  
 TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

DIMENSIONS: 117 x 17 x 90 mm

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

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

0000000000

**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, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

0000000000

Actual size



**14 TABLETS**  
 Strawberry Flavor  
 ONE 14-DAY COURSE OF TREATMENT

0000000000

No Lacquer →

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

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

No Lacquer ←

NDC 64239-181-01



D-55

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

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

D-55

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

Drug Facts	Drug Facts (continued)	Drug Facts (continued)
<p><b>Active ingredient (in each tablet)</b>            Lansoprazole 15mg</p> <p><b>Purpose</b>            Acid reducer</p> <p><b>Use</b>            ■ 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><b>Warnings</b>  <b>Allergy alert:</b> do not use if you are allergic to lansoprazole  <b>Do not use</b> 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.  <b>Ask a doctor before use if you have</b>            ■ 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  <b>Ask a doctor or pharmacist before use if you are taking</b>            ■ 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><b>Stop use and ask a doctor if</b>            ■ your heartburn continues or worsens            ■ you need to take this product for more than 14 days            ■ you need to take more than 1 course of treatment every 4 months            ■ you get diarrhea</p> <p><b>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)</b></p> <p><b>Directions</b>            ■ 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><b>14-Day Course of Treatment</b>            ■ 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><b>Repeated 14-Day Course (if needed)</b>            ■ 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><b>Other information</b>            ■ 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><b>Drug Facts (continued)</b>  <b>Questions or comments? 1-800-719-9260</b></p>

Batch No  
 EXP

**MODIFIED FORMAT**

**TYPE SIZES:**  
 TITLE: 9 pt Helvetica Bold Cond. Oblique  
 TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
 (continued) 7.5 pt Helvetica Medium Cond.  
 HEADINGS: 8 pt Helvetica Bold Cond. Oblique  
 SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique  
 TEXT: 6 pt Helvetica Medium Cond.  
 LEADING: 6.5 pt  
 BULLETS: 5 pt Square with 2 M'S spacing between statements  
 TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

DIMENSIONS: 117 x 17 x 90 mm

A B C D E F G H

Batch No  
EXP



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

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

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

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

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

D-28

NDC 64299-181-02

Actual size



28 TABLETS  
Strawberry Flavor  
TWO 14-DAY COURSES OF TREATMENT

**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

**Drug Facts**

**Active ingredient (in each tablet)**  
Lansoprazole 15mg

**Purpose**  
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 mofetil (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

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

**MODIFIED FORMAT**

**TYPE SIZES:**  
TITLE: 9 pt Helvetica Bold Cond. Oblique  
TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
(continued) 7.5 pt Helvetica Medium Cond.  
HEADINGS: 8 pt Helvetica Bold Cond. Oblique  
SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique  
TEXT: 6 pt Helvetica Medium Cond.  
LEADING: 6.5 pt  
BULLETS: 5 pt Square with 2 M'S spacing between statements  
TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
HEAVY LINES: 1.5 pt  
HAIRLINES: 0.5 pt

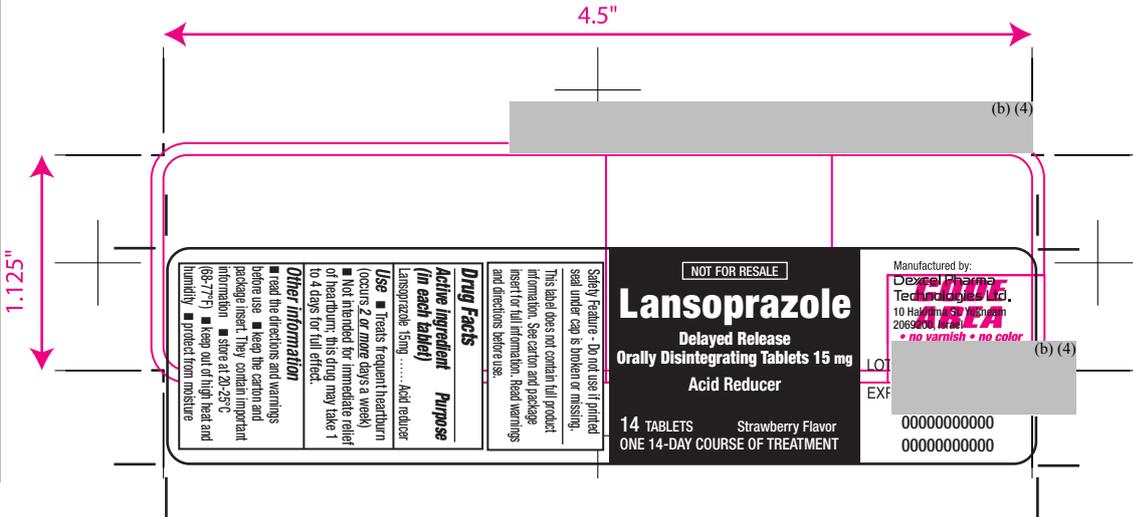
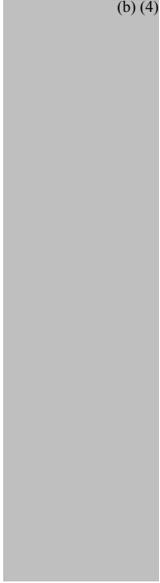
DIMENSIONS: 120 x 42 x 94 mm

No Lacquer →

← No Lacquer



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



Rev 1.44



**MODIFIED FORMAT**

**TYPE SIZES:**  
 TITLE: 8.5 pt Helvetica Bold Cond. Oblique  
 HEADINGS: 7.5 pt Helvetica Bold Cond. Oblique  
 TEXT: 6 pt Helvetica Medium Cond.  
 LEADING: 6 pt  
 BULLETS: 5 pt  
 LINES: 0.75 pt





Proposed Draft Labeling  
 NDA 208025  
 Lansoprazole Delayed Release Orally  
 Disintegrating Tablets, 15 mg  
 14 Tablets (Bottle carton)

This labeling has been formatted to comply with the FDA's final rule for labeling requirements 21 CFR 201.66 (c) 1-9 and 21 CFR 201.66 (d) 1-9. This rule sets the standard for labeling sequence, format and content.

Dexcel will place their own barcode on the inner flaps.

No Lacquer



**MODIFIED FORMAT**  
 TYPE SIZES:  
 TITLE: 9 pt Helvetica Bold Cond. Oblique  
 TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
 (continued) 7.5 pt Helvetica Medium Cond.  
 HEADINGS: 8 pt Helvetica Bold Cond. Oblique  
 SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique  
 TEXT: 6 pt Helvetica Medium Cond.  
 LEADING: 6.5 pt  
 BULLETS: 5 pt Square with 2 M'S spacing between statements  
 TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

DIMENSIONS: 81.5 x 40.5 x 57.2 mm

**Safety Feature - Do not use if printed seal under cap is broken or missing.**

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

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

**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

**Drug Facts (continued)**  
**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  
 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

**Drug Facts (continued)**  
 ■ 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  
**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, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate  
**Questions or comments?**  
 1-800-719-9260

1 bottle inside NDC 64239-181-04  
**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 Actual size

LOT NO. **CODE AREA**  
 EXP.

A  
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No Lacquer

Proposed Draft Labeling  
 NDA 208025  
 Lansoprazole Delayed Release Orally  
 Disintegrating Tablets, 15 mg  
 14 Tablets (Bottle carton)

This labeling has been formatted to comply with the FDA's final rule for labeling requirements 21 CFR 201.66 (c) 1-9 and 21 CFR 201.66 (d) 1-9. This rule sets the standard for labeling sequence, format and content.

Dexcel will place their own barcode on the inner flaps.

No Lacquer



**MODIFIED FORMAT**  
 TYPE SIZES:  
 TITLE: 9 pt Helvetica Bold Cond. Oblique  
 TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
 (continued) 7.5 pt Helvetica Medium Cond.  
 HEADINGS: 8 pt Helvetica Bold Cond. Oblique  
 SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique  
 TEXT: 6 pt Helvetica Medium Cond.  
 LEADING: 6.5 pt  
 BULLETS: 5 pt Square with 2 M/S spacing between statements  
 TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

DIMENSIONS: 81.5 x 40.5 x 57.2 mm

Proposed Draft Labeling  
 NDA 208025  
 Lansoprazole Delayed Release Orally  
 Disintegrating Tablets, 15 mg  
 28 Tablets (Bottle carton)



**MODIFIED FORMAT**

**TYPE SIZES:**  
 TITLE: 9 pt Helvetica Bold Cond. Oblique  
 TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
 (continued) 7.5 pt Helvetica Medium Cond.  
 HEADINGS: 8 pt Helvetica Bold Cond. Oblique  
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 BULLETS: 5 pt Square with 2 M'S spacing between statements  
 TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

DIMENSIONS: 81.5 x 40.5 x 88.9 mm

Proposed Draft Labeling  
 NDA 208025  
 Lansoprazole Delayed Release Orally  
 Disintegrating Tablets, 15 mg  
 28 Tablets (Bottle carton)



**MODIFIED FORMAT**

**TYPE SIZES:**  
 TITLE: 9 pt Helvetica Bold Cond. Oblique  
 TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
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 TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

DIMENSIONS: 81.5 x 40.5 x 88.9 mm

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

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

Safety Feature - Do not use if printed  
 seal under cap is broken or missing.

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

2 bottles inside NDC 64239-181-05

**Lansoprazole**  
 Delayed Release  
 Orally Disintegrating Tablets 15 mg  
 Acid Reducer  
 28 TABLETS Strawberry Flavor  
 TWO 14-DAY COURSES OF TREATMENT



**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

**Drug Facts (continued)**

**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

**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.

**Drug Facts (continued)**

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

**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, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

**Questions or comments? 1-800-719-9260**

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**Drug Facts (continued)**  
**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, 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, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate  
**Questions or comments?**  
 1-800-719-9260

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

3 bottles inside NDC 64239-181-06

# 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**



Actual size



LOT NO.  
EXP.

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**Safety Feature -**  
**Do not use if printed**  
**seal under cap is**  
**broken or missing.**

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

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

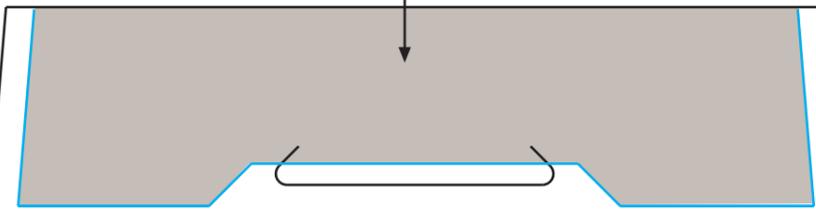
**Use**  
 ■ treats frequent heartburn (occurs 2 or more days a week)  
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect.

**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 mofetil (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.

No Lacquer





No Lacquer

**Proposed Draft Labeling**  
**NDA 208025**  
**Lansoprazole Delayed Release Orally**  
**Disintegrating Tablets, 15 mg**  
**42 Tablets (Bottle carton)**

**MODIFIED FORMAT**  
**TYPE SIZES:**  
 TITLE: 9 pt Helvetica Bold Cond. Oblique  
 TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
 (continued) 7.5 pt Helvetica Medium Cond.  
 HEADINGS: 8 pt Helvetica Bold Cond. Oblique  
 SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique  
 TEXT: 6 pt Helvetica Medium Cond.  
 LEADING: 6.5 pt  
 BULLETS: 5 pt Square with 2 M'S spacing between statements  
 TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

DIMENSIONS: 81.5 x 40.5 x 122.6 mm

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



Proposed Draft Labeling  
 NDA 208025  
 Lansoprazole Delayed Release Orally  
 Disintegrating Tablets, 15 mg  
 42 Tablets (Bottle carton)

**MODIFIED FORMAT**

**TYPE SIZES:**  
 TITLE: 9 pt Helvetica Bold Cond. Oblique  
 TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique  
 (continued) 7.5 pt Helvetica Medium Cond.  
 HEADINGS: 8 pt Helvetica Bold Cond. Oblique  
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 TELEPHONE #: 6.5 pt Helvetica Bold Cond.  
 HEAVY LINES: 1.5 pt  
 HAIRLINES: 0.5 pt

DIMENSIONS: 81.5 x 40.5 x 122.6 mm

Proposed Draft Package insert  
NDA 208025  
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg

# 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.



INSERT TEXT

type size:

TITLE: 28 pt Helvetica Black Cond.

SUBTITLE: 16 pt Helvetica Black Cond.

HEADINGS: 10 pt Helvetica Black Cond.

SUBHEADINGS: 10 pt Helvetica Bold Cond.

TEXT: 9.5 pt Helvetica Medium Cond.

### 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

**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**

Manufactured by:  
Dexcel Pharma Technologies Ltd.  
10 Hakidma St. Yokneam 2069200, Israel  
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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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KAREN M MAHONEY  
06/07/2016