



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

Batch No.  
EXP  
8U174 FA C5

**CODE AREA**

<p><b>Drug Facts</b></p> <p><b>Lansoprazole 15 mg (in each tablet)</b> Acid Reducer</p> <p><b>Use</b></p> <ul style="list-style-type: none"> <li>■ treats frequent heartburn (occurs 2 or more days a week)</li> <li>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>■ Allergy alert: do not use if you are allergic to lansoprazole</li> <li>■ 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.</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ liver disease</li> <li>■ had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>■ heartburn with <b>lightheadedness, sweating or dizziness</b></li> <li>■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness</li> <li>■ frequent wheezing, particularly with heartburn</li> <li>■ unexplained weight loss</li> <li>■ nausea or vomiting</li> <li>■ stomach pain</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>■ warfarin (blood-thinning medicine)</li> <li>■ digoxin (heart medicine)</li> <li>■ prescription antifungal or anti-yeast medicines</li> <li>■ theophylline (asthma medicine)</li> <li>■ tacrolimus or mycophenolate mofetil (immune system medicines)</li> <li>■ atazanavir (medicine for HIV infection)</li> <li>■ methotrexate (arthritis medicine)</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ your heartburn continues or worsens</li> <li>■ you need to take this product for more than 14 days</li> <li>■ you get diarrhea</li> <li>■ you develop a rash or joint pain</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Purpose</b></p> <p>Acid Reducer</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ adults 18 years of age and older</li> <li>■ this product is to be used once a day (every 24 hours), every day for 14 days</li> <li>■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</li> </ul> <p><b>14-Day Course of Treatment</b></p> <ul style="list-style-type: none"> <li>■ take 1 tablet before eating in the morning</li> <li>■ do not crush or chew tablets</li> <li>■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.</li> </ul> <p><b>Repeated 14-Day Course (if needed)</b></p> <ul style="list-style-type: none"> <li>■ you may repeat a 14-day course every 4 months</li> <li>■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</li> <li>■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ read the directions, warnings and package insert before use</li> <li>■ keep the carton and package insert. They contain important information.</li> <li>■ store at 20-25°C (68-77°F)</li> <li>■ protect product from moisture</li> </ul> <p><b>Inactive ingredients</b></p> <p>ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopollose, flavor, hypromellose, hypromellose phthalate, maleic anhydride, mannitol, magnesium, microcrystalline cellulose, polyacrylate 80, 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

**Treats Frequent Heartburn**

**New Dosage Form!**

**24 Hour**

**Lansoprazole**

**Delayed Release**

**Orally Disintegrating Tablets 15 mg**

**Acid Reducer**

- May take 1 to 4 days for full effect

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

**Melts in your mouth**  
Dissolves without water

**15** Actual size

MELTech™  
Melts In Your Mouth

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

**Strawberry Flavor**

**Questions or comments? 1-800-779-9260.**  
Weekdays 7:30 AM to 5:00 PM EST

**Drug Facts (continued)**




Made in Israel

Manufactured by:  
Cexxel Pharma Technologies Ltd  
10 Haklita Street, Yokneam 2069200, Israel

**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**

















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



Made in Israel  
Manufactured by:  
Dexcel 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 (continued)**

**Inactive ingredients** ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, maize maldextrin, mannitol, magnesium stearate, microcrystalline cellulose, polyacrylate, polyacrylate 80, propylene glycol, silicon dioxide, 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 15 mg, 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  
**requent 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)

**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 use for more than 14 days  
■ do not take more than 1 tablet a day  
■ 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.

**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.

Batch No. 8U155 FA C5-J  
EXP



Made in Israel  
Manufactured by:  
Dexcel 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 (continued)**

**Inactive ingredients** ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, maize maldextrin, mannitol, magnesium stearate, microcrystalline cellulose, polyacrylate, polyacrylate 80, propylene glycol, silicon dioxide, 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 15 mg, 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  
**requent 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)

**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 use for more than 14 days  
■ do not take more than 1 tablet a day  
■ 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.

**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.

Batch No. 8U155 FA C5-J  
EXP



Made in Israel  
Manufactured by:  
Dexcel 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 (continued)**

**Inactive ingredients** ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, maize maldextrin, mannitol, magnesium stearate, microcrystalline cellulose, polyacrylate, polyacrylate 80, propylene glycol, silicon dioxide, 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 15 mg, 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  
**requent 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)

**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 use for more than 14 days  
■ do not take more than 1 tablet a day  
■ 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.


**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.

Batch No. 8U155 FA C5-J  
EXP



Made in Israel  
Manufactured by:  
Dexcel 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 (continued)**

**Inactive ingredients** ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, maize maldextrin, mannitol, magnesium stearate, microcrystalline cellulose, polyacrylate, polyacrylate 80, propylene glycol, silicon dioxide, 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 15 mg, 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  
**requent 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)

**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 use for more than 14 days  
■ do not take more than 1 tablet a day  
■ 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.

**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.

Batch No. 8U155 FA C5-J  
EXP

**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 and 6.8 pt  
**BULLETS:** 5 pt Square  
**TELEPHONE #:** 6 pt Helvetica Neue 77 Bold Condensed  
**HEAVY LINES:** 1.5 pt  
**HAIRLINES:** 0.5 pt



**Proposed Draft 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 Hakdima Street, Yokneam 2069200, Israel  
Manufactured by:  
Dexcel Pharma Technologies Ltd  
Made in Israel

**Drug Facts (continued)**

**Inactive ingredients** ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, 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



Batch No.  
EXP  
8U155 FA C5-B

CODE AREA

**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

**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  
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

**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

■ 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.  
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness

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

**Active ingredient (in each tablet)** Lansoprazole 15 mg, Acid Reducer

**Purpose**

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

Treats Frequent Heartburn

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release  
Orally Disintegrating Tablets 15 mg

Acid Reducer

■ May take 1 to 4 days for full effect

42 TABLETS

THREE 14-DAY COURSES  
OF TREATMENT



Melts In Your Mouth

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

Value 3 Pack



Strawberry  
Flavor



Melts in your mouth  
Dissolves without water

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 and 6.8 pt  
BULLETS: 5 pt Square  
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed  
HEAVY LINES: 1.5 pt  
HAIRLINES: 0.5 pt







**Proposed Draft 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.

Dexcel Pharma Technologies Ltd  
10 Hakdama Street, Yokneam 2069200, Israel

Manufactured by:  
Made in Israel

**Drug Facts** (continued)

**Inactive ingredients** ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, 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  
8U130 FA C5-P

<p><b>Drug Facts</b> (continued)</p> <p><b>Stop use and ask a doctor if</b> ■ your heartburn continues or worsens</p> <p>■ you need to take this product for more than 14 days</p> <p>■ you need to take more than 1 course of treatment every 4 months</p> <p>■ you get diarrhea</p> <p>■ you develop a rash or joint pain</p> <p><b>If pregnant or breast-feeding</b>, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>	<p><b>Directions</b></p> <p>adults 18 years of age and older</p> <p>this product is to be used once a day (every 24 hours), every day for 14 days</p> <p>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></p> <p>take 1 tablet before eating in the morning</p> <p><b>do not crush or chew tablets</b></p> <p>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</p> <p>do not take more than 1 tablet a day</p> <p>do not use for more than 14 days unless directed by your doctor</p> <p>do not take this medicine with alcohol</p> <p><b>Repeated 14-Day Course (if needed)</b></p> <p>you may repeat a 14-day course every 4 months</p> <p><b>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</b></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><b>Warnings</b></p> <p><b>Allergy alert:</b> do not use if you are allergic to lansoprazole</p> <p><b>Do not use</b></p> <p>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><b>Ask a doctor before use if you have</b></p> <p>liver disease</p> <p>heartburn over 3 months. This may be a sign of a more serious condition.</p> <p>heartburn with <b>lightheadedness, sweating or dizziness</b></p> <p>chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</p> <p><b>Frequent chest pain</b></p> <p>frequent wheezing, particularly with heartburn</p> <p>unexplained weight loss</p> <p>nausea or vomiting</p> <p>stomach pain</p>	<p><b>Use</b></p> <p>Take frequent heartburn (occurs 2 or more days a week)</p> <p>not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p>
<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> Lansoprazole 15 mg</p> <p><b>Purpose</b> Acid Reducer</p>		<p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <p>warfarin (blood-thinning medicine)</p> <p>prescription antifungal or anti-yeast medicines</p> <p>digoxin (heart medicine)</p> <p>theophylline (asthma medicine)</p> <p>tacrolimus or mycophenolate mofetil (immune system medicines)</p> <p>atazavir (medicine for HIV infection)</p> <p>methotrexate (arthritis medicine)</p>	

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

Treats Frequent Heartburn

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg

Acid Reducer

■ May take 1 to 4 days for full effect

28 TABLETS

TWO 14-DAY COURSES OF TREATMENT



Melts In Your Mouth

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

Bonus Size! 14 Free



Strawberry Flavor

28 TABLETS

TWO 14-DAY COURSES OF TREATMENT

Melts in your mouth

Dissolves without water



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 and 6.8 pt

BULLETS: 5 pt Square

TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt







**Proposed Draft 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.

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

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

**CODE AREA**

Batch No.  
EXP  
8U155 FA C5-N

**Drug Facts**  
**Active ingredient (in each tablet)** Lansoprazole 15 mg, Acid Reducer

**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  
■ 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.  
■ 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  
■ 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 cyclosporine (immunosuppressant medicines)  
■ atazanavir (medicine for HIV infection)  
■ methotrexate (arthritis medicine)

**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.

**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  
■ 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

**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

**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  
■ 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

**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

**MELTech™**  
Melts In Your Mouth

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

**Bonus Size!**  
**14 Tablets Free**

**24 Hour**

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

**Acid Reducer**  
■ May take 1 to 4 days for full effect

**42 TABLETS**    THREE 14-DAY COURSES OF TREATMENT

**Melts in your mouth**  
Dissolves without water

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) 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 and 6.8 pt**  
**BULLETS: 5 pt Square**  
**TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed**  
**HEAVY LINES: 1.5 pt**  
**HAIRLINES: 0.5 pt**





**Proposed Draft 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 Hakdima Street, Yokneam 2069200, Israel  
Manufactured by:  
Cexcel Pharma Technologies Ltd  
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, fumed, hypromellose, hypromellose phthalate, maize maltoдекtrin, mannitol, magnesium stearate, microcrystalline cellulose, polyborate 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 15 mg, 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  
■ 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:  
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  
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 cyclosporine (immunosuppressant medicines)  
atazanavir (medicine for HIV infection)  
methotrexate (arthritis medicine)

**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.

**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

**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  
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.

**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

**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).

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

**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

**Treats Frequent Heartburn**

**New Dosage Form!**

**24 Hour**

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

**Acid Reducer**  
■ May take 1 to 4 days for full effect

**42 TABLETS** THREE 14-DAY COURSES OF TREATMENT

**Melts in your mouth**  
Dissolves without water

**MELTech™**  
Melts In Your Mouth

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

**Bonus! 14 Tablets FREE**

**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)  
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 and 6.8 pt  
BULLETS: 5 pt Square  
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed  
HEAVY LINES: 1.5 pt  
HAIRLINES: 0.5 pt

**Proposed Draft Labeling**  
**NDA 208025**  
**Lansoprazole Delayed Release Orally**  
**Disintegrating Tablets, 15 mg**  
**Package Insert**

**Front**

Treats Frequent Heartburn

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

- May take 1 to 4 days for full effect

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.



**Back**

**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 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 Street, Yokneam 2069200, Israel

: 80100 00 J2

