

5-16-17

5-16-17

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

5-16-17

5-16-17

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

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Lansoprazole 15 mg.....Acid Reducer</p> <p>Use</p> <ul style="list-style-type: none"> ■ 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>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with high blood pressure, swelling or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> ■ warfarin (blood-thinning medicine) ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or cyclosporine (immunosuppressant) ■ dextazavir (medication for HIV infection) ■ methotrexate (methotrexate) (arthritis medicine) 	<p>Directions</p> <ul style="list-style-type: none"> ■ adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ take 1 to 4 days for full effect, although some people may get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol <p>Repeated 14-Day Course (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition. 	<p>Other information</p> <ul style="list-style-type: none"> ■ keep the carton and package insert. They contain important information. ■ keep product out of high heat and humidity. ■ store at 20-25°C (68-77°F) ■ protect product from moisture
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size

HAIRLINES: 0.5 pt

<p>Drug Facts (continued)</p> <p>Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltoedextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, poly sorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>	<p>Questions or comments? 1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST</p> <p>Made in Israel</p> <p>Manufactured by: Dexel Pharmaceuticals Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p> <p>*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.</p>
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[illegible]



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.

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


STANDARD FORMAT

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5-16-17

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

<p>Batch No.</p> <p>EXP</p> <p>8U130 FA C5-J</p> <p style="text-align: center;">CODE AREA</p> 		<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you develop a rash or joint pain ■ you get diarrhea <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p> <p>Directions</p> <ul style="list-style-type: none"> ■ adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol! <p>Repeated 14-Day Course (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor ■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition. <p>Other information</p> <ul style="list-style-type: none"> ■ 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>Drug Facts</p> <p>Active ingredient (in each tablet)</p> <p>Lansoprazole 15 mg.....<i>Acid Reducer</i></p> <p>Use</p> <ul style="list-style-type: none"> ■ 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>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <ul style="list-style-type: none"> ■ 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>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> ■ warfarin (blood-thinning medicine) ■ prescription anti-fungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ aciclovir or mycophenolate mofetil (immune system medicines) ■ azacitidine (medicine for HIV infection) ■ methotrexate (arthritis medicine) 		<p>Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST</p> <hr/> <p>Drug Facts (continued)</p> <p>Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltoideextrin, maltitol, mannitol, microcrystalline cellulose, polyvinyl glycol, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>		<p>Made in Israel</p> <p>Manufactured by: Dexcel Pharma Technologies Ltd 10 Hakdama Street, Yokneam 2069200, Israel</p> <p>*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.</p>	
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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

MELTech™
Melts In Your Mouth

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

Child-resistant


Strawberry
Flavor

Melts in your mouth
Dissolves without water


Actual
size

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HAIRLINES: 0.5 pt

<p>Drug Facts (continued)</p> <p>Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, croscopollose, hypromellose, hypromellose phtalate, maize maltodextrin, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, sodium stearyl fumarate, sorbitol, sucralose, talc, titanium dioxide, triethyl citrate</p>	<p>Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST</p> <p>Made in Israel</p> <p>Manufactured by: Dexcel Pharma Technologies Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p> <p>*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.</p>
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Drug Facts (continued)

Inactive ingredients: ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscapellon, polyvinylpyrrolidone K90, polyethylene glycol, polysorbate 80, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide, triethyl citrate.

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

Drug Facts (continued)

Stop use and ask a doctor if: ■ your heartbeat 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

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
■ if many 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. Hearburn 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.
■ keep the carton at 25-27°C (68-77°F) ■ keep product out of high heat and humidity
■ protect product from moisture

CODE AREA



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.



Reference ID: 4188168

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5-16-17



0 00000 00000 0

Lansoprazole

Delayed Release Orally Disintegrating Tablets 15mg

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

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



<p><u>Drug Facts</u> (continued)</p> <p><u>Inactive ingredients</u> ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, poly sorbate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>	<p><u>Questions or comments?</u> 1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST</p>
<p>Made in Israel</p> <p>Manufactured by: Dexcel Pharmaceuticals Ltd 10 Hakidma Street, Yokneam 2069200, Israel</p>	<p>*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.</p>

Using P-123 (continued)

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you get diarrhea
- you need to take more than 1 course of treatment every 4 months
- 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
- 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 without being directed by your doctor

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 can and package insert. They contain important information.
- keep product out of high heat and humidity
- product product from moisture

Batch No.

EXP

8U155 FA C5-B

CODE AREA



5-16-17

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**
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BULLETS: 5 pt Square
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HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

5-16-17

Lansoprazole

**Delayed Release
Orally Disintegrating Tablets 15 mg**



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
Dissolves without water



Strawberry Flavor



Actual size



MELTech™
Melts In Your Mouth

Compare to the active ingredient in Prevacid® 24 HR*

**Buy One 14 Count,
Get One 14 Count Free!**

Drug Facts (continued)

Active ingredient (in each tablet)
Lansoprazole 15 mg.....**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
■ 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; spreading to arms, neck or shoulders; or lightheadedness
■ 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 mycophenolate mofetil (immune system medicines)
■ zalcitabine (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

Drug Facts (continued)

Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscarmellose sodium, hydroxypropyl methylcellulose, hypromellose, polyvinylpyrrolidone, polyethylene glycol, polysorbate 80, propylene glycol, silicon dioxide, sodium stearoyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

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

Batch No. **EXP** **8U130 FA C5-K**

CODE AREA

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

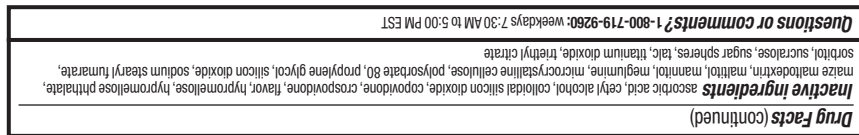
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed

HEAVY LINES: 1.5 pt

HAIRLINES: 0.5 pt

5-16-17

Proposed Draft Labeling NDA 208025



8U130 FA C5-R

Batch No.

EXP

<p>Drug Facts</p> <p>Active ingredient (in each tablet)</p> <p>Lansoprazole 15 mg.....Acid Reducer</p> <p>Purpose</p>	<p>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Do not use</p> <p>black stools. These may be signs of a serious condition. See your doctor.</p> <p>If you have trouble or pain swallowing food, vomiting with blood, or bloody or</p> <p>Ask a doctor before use if you have</p> <p>liver disease</p> <p>had heartburn over 3 months. This may be a sign of a more serious condition.</p> <p>heartburn with nighttime heartburn, sweating or dizziness</p> <p>chest pain or shoulder pain with shortness of breath, sweating, pain</p> <p>spreading to arms, neck or shoulders; or right-headedness</p> <p>frequent chest pain</p> <p>frequent wheezing, particularly with heartburn</p> <p>unexplained weight loss</p> <p>nausea or vomiting</p> <p>stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking</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>ecardium or mycophenolate mofetil (immune system medicines)</p> <p>zalcitabine (medicine for HIV infection)</p> <p>methexate (arthritis medicine)</p>	<p>Directions</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 weeks for full effect, although some people get complete</p> <p>relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment</p> <p>take 1 tablet before eating in the morning</p> <p>do not crush or chew tablets</p> <p>place the tablet on tongue; tablet disintegrates, with or without water.</p> <p>the tablet 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>Repeated 14-Day Course (if needed)</p> <p>you may repeat a 14-day course every 4 months</p> <p>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>children under 18 years of age; ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information</p> <p>read the directions, warnings and package insert before use</p> <p>store at 20-25°C (68-77°F).</p> <p>keep product out of high heat and humidity.</p>	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <p>your heartburn continues or worsens</p> <p>you need to take this product for more than 14 days</p> <p>you develop a rash or joint pain</p> <p>you get diarrhea</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>	<p>Directions</p> <p>adults 18 years of age and older</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 weeks for full effect, although some people get complete</p> <p>relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment</p> <p>take 1 tablet before eating in the morning</p> <p>do not crush or chew tablets</p> <p>place the tablet on tongue; tablet disintegrates, with or without water.</p> <p>the tablet 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>Repeated 14-Day Course (if needed)</p> <p>you may repeat a 14-day course every 4 months</p> <p>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>children under 18 years of age; ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information</p> <p>read the directions, warnings and package insert before use</p> <p>store at 20-25°C (68-77°F).</p> <p>keep product out of high heat and humidity.</p>	<p>Drug Facts</p> <p>Active ingredient (in each tablet)</p> <p>Lansoprazole 15 mg.....Acid Reducer</p> <p>Purpose</p>	<p>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Do not use</p> <p>black stools. These may be signs of a serious condition. See your doctor.</p> <p>If you have trouble or pain swallowing food, vomiting with blood, or bloody or</p> <p>Ask a doctor before use if you have</p> <p>liver disease</p> <p>had heartburn over 3 months. This may be a sign of a more serious condition.</p> <p>heartburn with nighttime heartburn, sweating or dizziness</p> <p>chest pain or shoulder pain with shortness of breath, sweating, pain</p> <p>spreading to arms, neck or shoulders; or right-headedness</p> <p>frequent chest pain</p> <p>frequent wheezing, particularly with heartburn</p> <p>unexplained weight loss</p> <p>nausea or vomiting</p> <p>stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking</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>ecardium or mycophenolate mofetil (immune system medicines)</p> <p>zalcitabine (medicine for HIV infection)</p> <p>methexate (arthritis medicine)</p>	<p>Directions</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 weeks for full effect, although some people get complete</p> <p>relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment</p> <p>take 1 tablet before eating in the morning</p> <p>do not crush or chew tablets</p> <p>place the tablet on tongue; tablet disintegrates, with or without water.</p> <p>the tablet 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>Repeated 14-Day Course (if needed)</p> <p>you may repeat a 14-day course every 4 months</p> <p>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>children under 18 years of age; ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p> <p>Other information</p> <p>read the directions, warnings and package insert before use</p> <p>store at 20-25°C (68-77°F).</p> <p>keep product out of high heat and humidity.</p>
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Lansoprazole

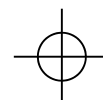
Delayed Release
Orally Disintegrating Tablets 15 mg



**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.



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

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

<p>Drug Facts</p> <p>Active ingredient (in each tablet)</p> <p>Lansoprazole 15 mg; _____ Acid Reducer</p> <p>Purpose</p>	<p>Use</p> <ul style="list-style-type: none"> ■ 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>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating, pain spreading to arms, neck or shoulders, or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ azathioprine (medicines for HIV infection) ■ methotrexate (antirheumatic medicine) 	<p>Directions</p> <ul style="list-style-type: none"> ■ adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol <p>Repeated 14-Day Course (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor <ul style="list-style-type: none"> ■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition. <p>Other information</p> <ul style="list-style-type: none"> ■ 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) ■ protect product from moisture 	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take this product for more than 14 days ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you develop a rash or joint pain</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>	<p>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ heartburn with lightheadedness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating, pain spreading to arms, neck or shoulders, or lightheadedness ■ frequent chest pain ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ azathioprine (medicines for HIV infection) ■ methotrexate (antirheumatic medicine) 	<p>Other information</p> <ul style="list-style-type: none"> ■ 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) ■ protect product from moisture
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Batch No.

Delayed Release



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
Dissolves without water

MELTech™
Melts In Your Mouth

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

Bonus! 14 Tablets FREE

**Strawberry
Flavor**

HAIRLINES: 0.5 pt

Drug Facts (continued)

Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you get diarrhea
- you get dizziness

Use only as directed:

- 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 (1-800-272-6222).

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
- take 1 tablet **or chew tablets**
- place the tablet on tongue, let it disintegrate, 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

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

children 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

CODE AREA



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.



Reference ID: 4188168

[illegible][illegible]

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

NDC 64239-181-03

Treats Frequent Heartburn

MELTech™
Melts In Your Mouth

New Dosage Form!

Compare to the active ingredient
in Prevacid® 24 HR*

Bonus Size! 14 Free

 **24 Hour**

Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg



Strawberry
Flavor

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



Actual
size

5-16-17

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

Drug Facts (continued)

Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopollose, flavor, hypromellose, hypromellose phthalate, maize malodextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, polysorbate 80, propylene glycol, titanium dioxide, triethyl citrate

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

Manufactured by:
Deccel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

Made in Israel

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

Drug Facts

Active ingredient (in each tablet) Lansoprazole 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
- 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 mycophenolate mofetil (immune system medicines)
- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

Other information

- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.
- unless directed by a doctor
- do not take for more than **14 days or more often than every 4 months**
- you may repeat a 14-day course every 4 months
- **Repeated 14-Day Course (if needed)**
- do not take this medicine with alcohol
- do not use for more than 14 days unless directed by your doctor
- do not take more than 1 tablet a day
- take every day for 14 days
- The tablets can also be swallowed whole with water.
- place the tablet on tongue; tablet disintegrates, with or without water.
- **do not crush or chew tablets**
- take 1 tablet before eating in the morning
- **14-Day Course of Treatment**
- relief of symptoms within 24 hours
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours
- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- if pregnant or breast-feeding, ask a health professional before use.
- **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).
- you get diarrhea
- you develop a rash or joint pain
- you need to take more than 1 course of treatment every 4 months
- you need to take this product for more than 14 days
- **Stop use and ask a doctor if** ■ your heartburn continues or worsens

Drug Facts (continued)

Directions

- take 1 tablet before eating in the morning
- **do not crush or chew tablets**
- place the tablet on tongue; tablet disintegrates, with or without water.
- The tablets can also be swallowed whole with water.
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not take this medicine with alcohol
- 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 64239-181-03

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 Free

Strawberry Flavor

15 Actual size

NDC 64239-181-03

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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

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<p>Drug Facts</p> <p>Active ingredient (in each tablet) Lansoprazole 15 mg.....Acid Reducer</p> <p>Purpose</p>	<p>Use</p> <ul style="list-style-type: none"> ■ 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>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness <p>Check pain</p> <ul style="list-style-type: none"> ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ ceftriaxone or mycophenolate mofetil (immune system medicines) ■ zalcitabine (medicine for HIV infection) ■ methotrexate (methotrexate tablets) 	<p>Directions</p> <ul style="list-style-type: none"> ■ adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours <p>14-Day Course of Treatment</p> <ul style="list-style-type: none"> ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol <p>Repeated 14-Day Course (if needed)</p> <ul style="list-style-type: none"> ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor <ul style="list-style-type: none"> ■ children under 11 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition. <p>Other Information</p> <ul style="list-style-type: none"> ■ 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 	<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if ■ 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 develop a rash or joint pain</p> <p>if pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>	<p>Warnings</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ 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>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition. ■ chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness <p>Check pain</p> <ul style="list-style-type: none"> ■ frequent wheezing, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain <p>Ask a doctor or pharmacist before use if you are taking</p> <ul style="list-style-type: none"> ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ ceftriaxone or mycophenolate mofetil (immune system medicines) ■ zalcitabine (medicine for HIV infection) ■ methotrexate (methotrexate tablets)
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Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15mg



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

Actual
size

MELTech™
Melts In Your Mouth

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

Bonus! 14 Tablets FREE

**Strawberry
Flavor**

5-16-17

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.



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

• 803.00 00 J2

