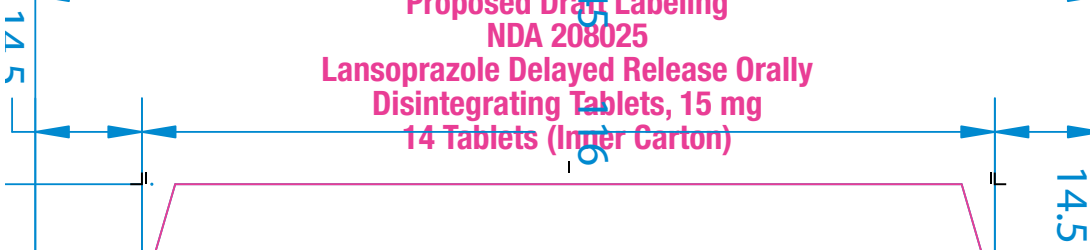


**Proposed Draft Labeling
NDA 208025**

**Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
14 Tablets (Inner Carton)**



<p>Drug Facts Active ingredient (in each tablet) Lansoprazole 15mg, Acid reducer</p> <p>Purpose 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).</p> <p>Directions <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 If may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours </p> <p>14-Day Course of Treatment <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 tablet can also be swallowed whole with water. take every day for 14 days do not take more than 1 tablet a day do not use for more than 14 days unless directed by your doctor do not take this medicine with alcohol </p> <p>Repeated 14-Day Course (if needed) <ul style="list-style-type: none"> do not take this medicine with alcohol do not take this medicine with alcohol do not take this medicine with alcohol </p> <p>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"> you may repeat a 14-day course every 4 months 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 <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 </p> <p>Inactive ingredients ascorbic acid, acetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, fawn, hypromellose, hypromellose phthalate, maleate maleobuxin, mannitol, mannitol, meglumine, microcrystalline cellulose, polyborate 80, polyethylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate</p>	<p>Use <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> <p>Warnings <ul style="list-style-type: none"> 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. </p> <p>Ask a doctor before use if you have <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, sweating or dizziness chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness chest pain recurrent wheezing, particularly with heartburn unexplained weight loss nausea or vomiting stomach pain </p> <p>Ask a doctor or pharmacist before use if you are taking <ul style="list-style-type: none"> warfarin (blood-thinning medicine) prescription anti-fungal or anti-yeast medicines digoxin (heart medicine) theophylline (asthma medicine) beta-blockers or mycophenolate mofetil (immune system medicines) atazanavir (medicine for HIV infection) methotrexate (arthritis medicine) </p> <p>Stop use and ask a doctor if <ul style="list-style-type: none"> your heartburn continues or worsens you need to take more than 1 course of treatment every 4 months you get diarrhea </p>
--	---

Batch No.
EXP : 8UJ74 00 2A - Y

CODE AREA

NOT FOR RESALE

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

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

24 Hour
Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg
Acid Reducer

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

14 TABLETS

One 14-day course of treatment

Strawberry
Flavor



Actual size

Made in Israel
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakdima Street, Yokneam 2089200, Israel

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

MODIFIED FORMAT

TYPE SIZES:
TITLE: 8 pt Helvetica Neue 77 Bold Condensed Oblique
TITLE (continued): 7 pt Helvetica Neue 77 Bold Condensed Oblique
 (continued) **7 pt Helvetica Neue 57 Condensed**
HEADINGS: 7 pt Helvetica Neue 77 Bold Condensed Oblique
SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed
TEXT: 6 pt Helvetica Neue 57 Condensed
LEADING: 6 pt
BULLETS: 5 pt Square with 2 M'S spacing between statements
TELEPHONE #: 6 pt Helvetica Neue 77 Bold Condensed
HEAVY LINES: 1.5 pt
HAIRLINES: 0.5 pt

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.

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

Drug Facts (continued)

Inactive ingredients (continued)
ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, ma mabedextrin, mannitol, magnesium, microcrystalline cellulose, polyborate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sor ol, 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 _____
: AUG 30 F A C2-Y

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 ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.

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

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

■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

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

Drug Facts

Active ingredient (in each tablet) Lansoprazole 15mg, 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
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.
Allergy alert: do not use if you are allergic to lansoprazole

Ask a doctor before use if you have
■ had heartburn over 3 months. This may be a sign of a more serious condition ■ liver disease ■ frequent chest pain ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness

Ask a doctor pharmacist before use if you are taking
■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ baclofen or meprobamate (muscle relaxant) ■ telaviv (antibiotic for HIV infection) ■ methotrexate (arthritis medicine)

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg



Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

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

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

Compare to the active ingredient in Prevacid® 24 HR*

New Dosage Form!

24 Hour

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer

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

28 TABLETS TWO 14-DAY COURSES OF TREATMENT

Strawberry Flavor

15 Actual size

STANDARD FORMAT

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

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



Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Drug Facts (continued)

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

Use

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

Warnings

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

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

Ask a doctor before use if you have

- liver disease
- had heartburn over 3 months. This may be a sign of a more serious condition
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- 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 cyclosporine (immunosuppressant medicines)
- atazanavir (medicine for HIV infection)
- methotrexate (arthritis medicine)

Other Information

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

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

Drug Facts (continued)

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

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.

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer

Melts in your mouth
Dissolves without water

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

42 TABLETS THREE 14-DAY COURSES OF TREATMENT

Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-03

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 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.

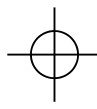
Cexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel

Manufactured by:
Made in Israel

Drug Facts (continued)

In active ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, croscopolone, flavor, hypromellose, hypromellose phthalate, ma e matedoextrin, methyl, mannitol, magnesium, microcrystalline cellulose, polysorbate 80, polypropylene glycol, silicon dioxide, sodium stearyl fumarate, sor, talc, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

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



CODE AREA

Batch No.
EXP
: AUG130 FA C2-YV

Drug Facts (continued)

Active ingredient (in each tablet) Lansoprazole 15mg; 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
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:
■ 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)

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg





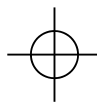
Other information
■ read the directions, warnings and package insert before use
■ keep the carton and package insert. They contain important information.
■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity
■ protect product from moisture

Directions
■ adults 18 years of age and older
■ this product is to be used once a day (every 24 hours), every day for 14 days
■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

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





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

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 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.

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg





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

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





NDC 64239-181-02

Compare to the active ingredient in Prevacid® 24 HR*

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release

Orally Disintegrating Tablets 15 mg

Acid Reducer

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

28 TABLETS

TWO 14-DAY COURSES OF TREATMENT



Strawberry Flavor



Orally Disintegrating Tablets

Actual size



STANDARD FORMAT

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

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

Batch No.
EXP
: AUJ155 FA CE-YV

CODE AREA

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg

Drug Facts (continued)

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

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

Warnings
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 **hightheadedness, 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)
■ zidovudine (medicine for HIV infection)
■ methotrexate (arthritis medicine)

Drug Facts (continued)

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

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.

Stop use and ask a doctor if ■ your heartburn continues or worsens
■ you need to take more than 1 course of treatment every 4 months
■ you get diarrhea

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).

Warnings
■ 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

Questions or comments? 1-800-719-9266; weekdays 7:30 AM to 5:00 PM EST

Manufactured by:
Cexcel Pharma Technologies Ltd
10 Hakdima Street, Yokneam 2069200, Israel

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



Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg

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

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



Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-03

New Dosage Form!

24 Hour Lansoprazole

**Delayed Release
Orally Disintegrating Tablets 15 mg**

Acid Reducer

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

42 TABLETS

THREE 14-DAY COURSES OF TREATMENT

Strawberry Flavor



Orally Disintegrating Tablets



Actual size

STANDARD FORMAT

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

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

<p>Batch No. EXP : AUJ55 FA C2-YN</p> <p style="text-align: center; color: red; font-weight: bold; font-size: 1.2em;">CODE AREA</p>	<p style="text-align: center;">Drug Facts (continued)</p> <p>Active ingredient (in each tablet) Lansoprazole 15mg, Acid reducer</p> <p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings Allergy alert: do not use if you are allergic to lansoprazole Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor. Ask a doctor before use if you have ■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition ■ heartburn with hightheadness, sweating or dizziness ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness ■ frequent chest pain, particularly with heartburn ■ unexplained weight loss ■ nausea or vomiting ■ stomach pain</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or cyclosporine (immunosuppressant medicines) ■ zidovudine (medicine for HIV infection) ■ methotrexate (arthritis medicine)</p> <p>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</p> <p>Directions ■ adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol</p> <p>Repeated 14-Day Course (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>■ children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.</p>	<p style="text-align: center; font-size: 2em; font-weight: bold;">Lansoprazole</p> <p style="text-align: center; font-weight: bold;">Delayed Release Orally Disintegrating Tablets 15 mg</p>
<p style="text-align: center;">*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</p> <p style="text-align: center;">Questions or comments? 1-800-719-9260; weekdays 7:30 AM to 5:00 PM EST</p>		

	<p style="font-size: 1.5em; font-weight: bold;">Lansoprazole</p> <p style="font-weight: bold;">Delayed Release Orally Disintegrating Tablets 15 mg</p> <p style="border: 1px solid black; padding: 2px; display: inline-block;">Safety Feature – Do not use if printed tablet blister unit is open or torn.</p> <p style="font-size: 0.8em;">KEEP THE CARTON AND PACKAGE INSERT. THEY CONTAIN IMPORTANT INFORMATION.</p>	
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<p style="font-weight: bold; color: red;">Bonus Size! 14 Tablets Free</p>	<p style="font-size: 0.8em;">Compare to the active ingredient in Prevacid® 24 HR*</p>
<p style="text-align: center; font-weight: bold;">New Dosage Form!</p> <p style="text-align: center; font-size: 1.5em; font-weight: bold;">24 Hour</p> <p style="text-align: center; font-size: 2.5em; font-weight: bold;">Lansoprazole</p> <p style="text-align: center; font-weight: bold;">Delayed Release Orally Disintegrating Tablets 15 mg</p> <p style="text-align: center; font-weight: bold;">Acid Reducer</p> <ul style="list-style-type: none"> ■ May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours ■ Clinically Proven To Treat Frequent Heartburn <p style="text-align: center; font-size: 1.5em; font-weight: bold;">42 TABLETS</p> <p style="text-align: center; font-size: 0.8em;">THREE 14-DAY COURSES OF TREATMENT</p>	<p style="text-align: center;">NDC 64239-181-03</p> <div style="text-align: center;">  <p style="font-size: 0.8em;">Strawberry Flavor</p>  <p style="font-size: 0.7em;">Actual size</p> </div>

STANDARD FORMAT

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

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

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

Inactive ingredients ascorbic acid, cetyl alcohol, colloidal silicon dioxide, copovidone, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maldextrin, maltitol, mannitol, meglumine, microcrystalline cellulose, poly(sorbate 80), propylene glycol, silicon dioxide, sodium lauryl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

⊕

CODE AREA

Batch No.
EXP
: 8U155 FA C2-YP

<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</p> <p>Purpose Acid reducer</p>	<p>Use</p> <p>■ treats 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>Warnings</p> <p>Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.</p> <p>Allergy alert: do not use if you are allergic to lansoprazole</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ 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) ■ zidovudine (medicines for HIV infection) ■ methotrexate (arthritis medicine) 	<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 days for full effect, although some people get complete relief of symptoms within 24 hours</p> <p>14-Day Course of Treatment</p> <p>■ take 1 tablet before eating in the morning</p> <p>■ do not crush or chew tablets</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>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>■ keep the carton and package insert. They contain important information.</p> <p>■ store at 20-25°C (68-77°F) ■ keep product out of high heat and humidity</p> <p>■ protect product from moisture</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.

⊕

Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg

⊕

Bonus Size! 14 Free

Compare to the active ingredient in Prevacid® 24 HR*

NDC 64239-181-03

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer

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

42 TABLETS

THREE 14-DAY COURSES OF TREATMENT

Strawberry
Flavor

15
Actual size

STANDARD FORMAT

TYPE SIZES:

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TITLE (continued): 8 pt Helvetica Neue 77 Bold Condensed Oblique

(continued) 8 pt Helvetica Neue 57 Condensed

HEADINGS: 8 pt Helvetica Neue 77 Bold Condensed Oblique

SUBHEADINGS: 6 pt Helvetica Neue 77 Bold Condensed

TEXT: 6 pt Helvetica Neue 57 Condensed

LEADING: 6.5 pt

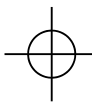
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HAIRLINES: 0.5 pt

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

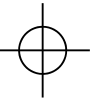


*This product is not manufactured or distributed by Novartis Consumer Health, Inc., distributor of Prevacid® 24 HR.

Decel Pharma Technologies Ltd
10 Hakdama 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, crospovidone, flavor, hypromellose, hypromellose phthalate, maize maltoedextrin, maltitol, mannitol, microcrystalline cellulose, polyborate 80, propylene glycol, silicon dioxide, sodium stearyl fumarate, sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate



CODE AREA

Batch No.
EXP
: AU155 FA C2-YR

Drug Facts (continued)

Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you get dizziness

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

1-4 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.

Repeated 1-4 Day Courses (if needed)
■ do not take for more than 14 days unless directed by your doctor ■ do not use for more than 14 days with alcohol

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 ■ you may repeat a 1-4-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months

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 (immunosuppressant medicines) ■ zidovudine (medication for HIV infection) ■ methotrexate (arthritis medicine)

Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition ■ heartburn with **hightheadedness, 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

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

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

Purpose
Acid reducer

Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg

Batch No.
EXP
: AU155 FA C2-YR

Drug Facts (continued)

Stop use and ask a doctor if ■ your heartburn continues or worsens ■ you need to take more than 1 course of treatment every 4 months ■ you get diarrhea ■ you get dizziness

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
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1-4 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.

Repeated 1-4 Day Courses (if needed)
■ do not take for more than 14 days unless directed by your doctor ■ do not use for more than 14 days with alcohol

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 ■ you may repeat a 1-4-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months

Ask a doctor before use if you are taking
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Warnings
Do not use if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
Ask a doctor before use if you have
■ liver disease ■ had heartburn over 3 months. This may be a sign of a more serious condition ■ heartburn with **hightheadedness, 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

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

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

Purpose
Acid reducer

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.



Bonus! + 14 Free

NDC 64239-181-03

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer

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

42 TABLETS

THREE 14-DAY COURSES OF TREATMENT



Strawberry Flavor



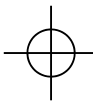
15 Actual size

Compare to the active ingredient in Prevacid® 24 HR*

STANDARD FORMAT

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

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.

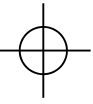
Manufactured by:
Dexcel Pharma Technologies Ltd
10 Hakdama Street, Yokneam 2069200, Israel

Made in Israel

Drug Facts (continued)

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

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



CODE AREA

Batch No. _____
EXP _____
: 8UJ55 FA C2-YS

<p>Drug Facts (continued)</p> <p>Purpose Lansoprazole 15mg, Acid reducer</p> <p>Use ■ treats frequent heartburn (occurs 2 or more days a week) ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</p> <p>Warnings 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</p> <p>Ask a doctor or pharmacist before use if you are taking ■ warfarin (blood-thinning medicine) ■ prescription antifungal or anti-yeast medicines ■ digoxin (heart medicine) ■ theophylline (asthma medicine) ■ tacrolimus or mycophenolate mofetil (immune system medicines) ■ zalcitabine (medicine for HIV infection) ■ methotrexate (arthritis medicine)</p>	<p>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</p> <p>14-Day Course of Treatment ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol</p> <p>Repeated 14-Day Courses (if needed) ■ you may repeat a 14-day course every 4 months ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor</p> <p>Children ■ adults 18 years of age and older ■ this product is to be used once a day (every 24 hours), every day for 14 days ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</p> <p>Directions 14-Day Course of Treatment ■ take 1 tablet before eating in the morning ■ do not crush or chew tablets ■ place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water. ■ take every day for 14 days ■ do not take more than 1 tablet a day ■ do not use for more than 14 days unless directed by your doctor ■ do not take this medicine with alcohol</p> <p>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</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.

Batch No. _____
EXP _____
: 8UJ55 FA C2-YS



Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg





Bonus! 14 Tablets FREE

NDC 64239-181-03

New Dosage Form!

24 Hour

Lansoprazole

Delayed Release
Orally Disintegrating Tablets 15 mg

Acid Reducer

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

42 TABLETS

THREE 14-DAY COURSES
OF TREATMENT



Strawberry
Flavor



15
Actual
Size



STANDARD FORMAT

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

Reference ID: 4094191

3-24-17

