CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208025Orig1s000

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

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

Lansoprazole
Delayed Release Orally
Disintegrating Tablets 15 mg
acid reducer
Push tablet through foil
Dexcel Pharma Technologies Ltd.
10 Hakidma St. Yokneam 2069000, Israel

6.5 pt Helvetica Black Cond.
5 pt Helvetica Bold Cond.
6 pt Helvetica Bold Cond.
6 pt Helvetica Medium

Reference ID: 3941618
**Proposed Draft Labeling**

**NDA 208025**

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

**Blister of 14 tablets**

<table>
<thead>
<tr>
<th>Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg and retarder</th>
<th>Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg and retarder</th>
<th>Lansoprazole Delayed Release Orally Disintegrating Tablets 15 mg and retarder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Push tablet through foil; Dexcel Pharma Technologies Ltd. 10 Hakimia St. Yokneam 2069200, Israel</td>
<td>Push tablet through foil; Dexcel Pharma Technologies Ltd. 10 Hakimia St. Yokneam 2069200, Israel</td>
<td>Push tablet through foil; Dexcel Pharma Technologies Ltd. 10 Hakimia St. Yokneam 2069200, Israel</td>
</tr>
</tbody>
</table>

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

Reference ID: 3941618
Drug Facts

Active ingredient (in each tablet) Lansoprazole 15mg

Acid reducer

Drug Facts (continued)

Warning: Do not use if you have ever had stomach ulcers or bleeding or black stools. These may be signs of a serious condition. See section 12.2.

Do not use this medicine with alcohol.

Do not use if you are allergic to lansoprazole or other ingredients in this medicine.

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 section 12.2.

Use the closed end of the blister unit to help ensure the tablets remain intact. Place the tablet on tongue; tablet disintegrates, with or without water.

The tablets can also be swallowed whole with water.

Each tablet contains:

Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg

14 Tablets

Proposed Draft Labeling

NDA 208025

Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg

14 Tablets

MODIFIED FORMAT

TITLE: 5 pt Helvetica Bold Cond. Oblique

TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique

(continued): 7.5 pt Helvetica Medium Cond.

HEADINGS: 8 pt Helvetica Bold Cond. Oblique

SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique

TEXT: 6 pt Helvetica Medium Cond.

LEADING: 6.5 pt

BULLETS: 5 pt Square with 2 M’S spacing between statements

TELEPHONE #: 6.5 pt Helvetica Bold Cond.

Actual format dimensions: 117 x 17 x 90 mm

Actual size

---

Reference ID: 3941618
**Drug Facts**

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

**Other information:**

- **Children under 18 years of age:** ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.
- **14-Day Course:**
  - This product is to be used once a day (every 24 hours), every day for 14 days.
  - **Take every day for 14 days**
  - **Do not crush or chew tablets**
  - **Stop use and ask a doctor if you get diarrhea**
  - **May take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours**
- **Repeated 14-Day Course (if needed):**
  - You may repeat a 14-day course every 4 months
  - **Do not use for more than 14 days unless directed by your doctor**
- **2 or more Treats Frequent Heartburn:**
  - Frequent heartburn occurs 2 or more days a week
  - You need to take more than 1 course of treatment every 4 months
- **Can Be Used:**
  - **For a 14-Day Course of Treatment**
  - **For More Than 14 Days:**
    - **If needed by a doctor**
    - You need to take this product for more than 14 days
    - You need to take this product for more than 14 days
- **Not Intended for Immediate Relief of Heartburn:**
  - This drug may take 1 to 4 days for full effect.
- **14-Day Course of Treatment:**
  - **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**
- **You may have heartburn over 3 months:**
  - This may be a sign of a more serious condition. See your doctor.
- **Ask a doctor before use if you have:**
  - **Uncontrolled nausea or vomiting**
  - **Nausea or vomiting with blood, vomiting with blood, vomiting with blood, vomiting with blood**
- **If you have trouble or pain swallowing food,**
  - **Vomiting with blood, vomiting with blood, vomiting with blood**
- **Contact a Poison Control Center right away (1-800-222-1222)**
- **Ask your doctor if you have:**
  - **Your heartburn continues or worsens**
  - **Chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness**
- **If you have trouble or pain swallowing food,**
  - **Vomiting with blood, vomiting with blood, vomiting with blood**
- **You have trouble or pain swallowing food,**
  - **Vomiting with blood, vomiting with blood, vomiting with blood**
- **Do not use if you are allergic to lansoprazole**

**Warnings**

- **Ask a doctor before use if you have:**
  - **Your doctor.**
  - **Bloody or black stools. These may be signs of a serious condition.**
  - **Ask a doctor before use if you are taking:**
    - **atazanavir (medicine for HIV infection)**
    - **tacrolimus or mycophenolate mofetil (immune system medicines)**
    - **digoxin (heart medicine)**
    - **prescription antifungal or anti-yeast medicines**
    - **warfarin (blood-thinning medicine)**

- **Drug Interactions:**
  - **Read the directions, warnings and package insert before use**
  - **Keep out of reach of children.**
  - **Contact a Poison Control Center right away (1-800-222-1222)**

**Dosage and Administration**

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

**Active Ingredient:**

- **Lansoprazole 15mg**

**Purpose:**

- **Acid reducer**
- **Drug Facts**
- **Inactive ingredients:**
- **Other information:**
- **Dosage and Administration**
- **Acid Reducer**
- **Lansoprazole 15mg**
- **Orally Disintegrating Tablets 15 mg**
- **Delayed Release**
- **Acid Reducer**
- **Delayed Release**
- **Orally Disintegrating Tablets 15 mg**

**Questions or comments?**

**Proposed Draft Labeling**

**NDA 208025**

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

**28 Tablets**

**HAIRLINES: 0.5 pt**

**HEAVY LINES: 1.5 pt**

**TELEPHONE #: 6.5 pt Helvetica Bold Cond.**

**LEADING: 6.5 pt**

**TEXT: 6 pt Helvetica Medium Cond.**

**SUBHEADINGS: 6 pt Helvetica Bold Cond. Oblique**

**HEADINGS: 8 pt Helvetica Bold Cond. Oblique**

**TITLE: 9 pt Helvetica Bold Cond. Oblique**

**TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique**

**BULLETS: 5 pt Square with 2 M'S spacing between statements**

**TYPE SIZES:**

**MODIFIED FORMAT**

**TYPE SIZES:**

**TITLE: 9 pt Helvetica Bold Cond. Oblique**

**TITLE (continued): 7.5 pt Helvetica Bold Cond. Oblique**

**TELEPHONE #: 6.5 pt Helvetica Bold Cond.**

**HEAVY LINES: 1.5 pt**

**HAIRLINES: 0.5 pt**

**DIMENSIONS: 130 x 62 x 84 mm**

Reference ID: 3941618
Proposed Draft Labeling
NDA 208025
Lansoprazole Delayed Release Orally
Disintegrating Tablets, 15 mg
Bottle Label
Dexel will place their own barcodes on the inner flap.
3 bottles inside

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg
Acid Reducer

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

42 Tablets
Strawberry Flavor
THREE 14-DAY COURSES OF TREATMENT

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

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

Drug Facts

Active ingredient (in each tablet) Purpose
Lansoprazole 15 mg

Inactive ingredients:
- saccharin sodium
- dextrose
- sodium saccharin
- citric acid
- edac acid
- sodium lauryl sulfate
- cornstarch
- sodium stearyl fumarate
- sorbitol, water, flavor
- and other inactive ingredients

Acid Reducer

3 bottles inside

Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg

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

MODIFIED FORMAT

TYPE SIZES:
D 6
D 5
D 4
D 3
D 2
D 1
D 0
C 3
C 2
C 1
C 0
B 3
B 2
B 1
B 0
A 3
A 2
A 1
A 0
Reference ID: 3941618
Proposed Draft Package insert
NDA 208025
Lansoprazole Delayed Release Orally Disintegrating Tablets, 15 mg

Lansoprazole
Delayed Release
Orally Disintegrating Tablets 15 mg
acid reducer

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

Please read the entire package insert before taking Lansoprazole Delayed Release Orally Disintegrating Tablets. Save for future reference.

How Lansoprazole delayed release orally disintegrating tablets Treats Your Frequent Heartburn
Lansoprazole delayed release orally disintegrating tablets stops acid production at the source—the pumps that release acid into the stomach. Lansoprazole delayed release orally disintegrating tablets is taken once a day (every 24 hours) every day for 14 days.

What You Can Expect When Taking Lansoprazole delayed release orally disintegrating tablets
Frequent heartburn can occur anytime during the 24-hour period (day or night). Take Lansoprazole delayed release orally disintegrating tablets in the morning before eating. Lansoprazole is clinically proven to treat frequent heartburn. Although some people get complete relief of symptoms within 24 hours, it may take 1 to 4 days for full effect. Make sure you take Lansoprazole delayed release orally disintegrating tablets every day for 14 days to treat your frequent heartburn.

Who Should Take Lansoprazole delayed release orally disintegrating tablets
Adults (18 years and older) with frequent heartburn—when you have heartburn 2 or more days a week.

Who Should NOT Take Lansoprazole delayed release orally disintegrating tablets
People who have one episode of heartburn a week or less, or who want immediate relief of heartburn.

How to Take Lansoprazole delayed release orally disintegrating tablets
14-DAY Course of treatment
- take 1 tablet before eating in the morning.
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor.
- do not take this medicine with alcohol

When to Take Lansoprazole delayed release orally disintegrating tablets Again
You may repeat a 14-day course of therapy every 4 months.

When to Talk to Your Doctor
Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.
Warnings and When to Ask Your Doctor

Allergy alert: Do not use if you are allergic to lansoprazole.

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

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

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

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

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

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

Tips for managing Heartburn
■ Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.
■ Eat slowly and do not eat big meals.
■ Do not eat late at night or just before bedtime.
■ Do not lie flat or bend over soon after eating.
■ Raise the head of your bed.
■ Wear loose-fitting clothing around your stomach.
■ If you are overweight, lose weight.
■ If you smoke, quit smoking.

Clinical studies prove that lansoprazole effectively treats frequent heartburn
In three clinical studies, lansoprazole was shown to be significantly better than placebo in treating frequent heartburn.

How Lansoprazole delayed release orally disintegrating tablets is Sold
This medicine is available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes contain one, two and three 14-day courses of treatment, respectively.

Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments About Lansoprazole delayed release orally disintegrating tablets
Call 1-800-719-9260

Manufactured by:
Darcel Pharma Technologies Ltd.,
10 Hakidma St. Yokneam 2069200, Israel
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
06/07/2016