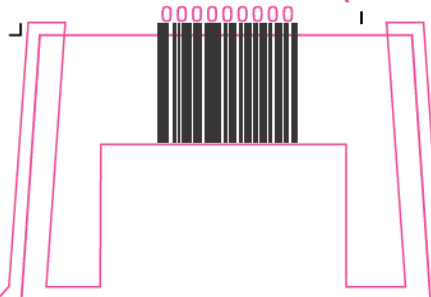




**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**14 Tablets (Bottle Carton)**



**Drug Facts (continued)**

- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine) ■ digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

**Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

**If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away, (1-800-222-1222)

**Directions**

- for 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; some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**

- swallow 1 tablet with a glass of water before eating in the morning
- 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
- swallow whole. Do not chew or crush tablets

**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

**Drug Facts (continued)**

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

**Other Information**

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

**Inactive Ingredients**  
 carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

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

**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight ■ Quit smoking



**FDA Approved**

**DIE CUT WINDOW**

Treats Frequent Heartburn! Occurring 2 Or More Days a Week

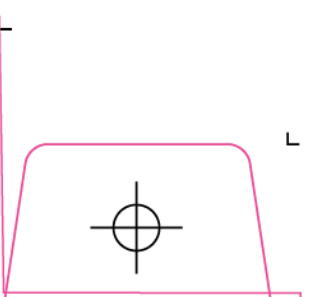
**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**

14 Tablets  
 One 14-day course of treatment  
 1 BOTTLE INSIDE

LOT NO. **CODE AREA**

EXP. : 915D5 FA CBB1



**Drug Facts**

**Active Ingredient (in each tablet) Purpose**  
 Omeprazole 20 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**

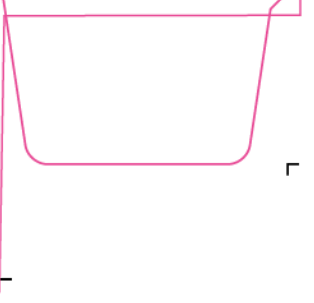
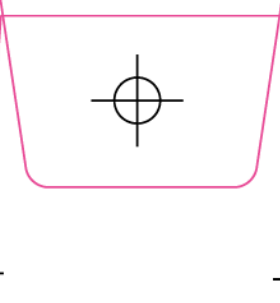
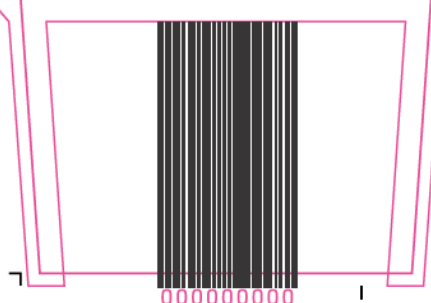
**Allergy alert:** Do not use if you are allergic to omeprazole

**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.
- 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, clopidogrel or cilostazol (blood-thinning medicines)



(b) (4)







**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**28 Tablets**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Drug Facts</b> (continued)</p> <p><b>Active ingredient (in each tablet)</b> Omeprazole 20 mg, acid reducer.</p> <p><b>Purpose</b> Treats frequent heartburn (occurs 2 or more days a week) 1 to 4 days for full effect.</p> <p><b>Warnings</b> Allergy alert: Do not use if you are allergic to omeprazole. Do not use if you have trouble or pain swallowing food, vomiting with blood, or blood or black stools. These may be signs of a serious condition. See your doctor.</p> <p><b>Use</b> Beads frequent heartburn (occurs 2 or more days a week) 1 to 4 days for full effect.</p> | <p><b>Drug Facts</b></p> <p><b>Warnings</b> Allergy alert: Do not use if you are allergic to omeprazole. Do not use if you have trouble or pain swallowing food, vomiting with blood, or blood or black stools. These may be signs of a serious condition. See your doctor.</p> <p><b>Use</b> Beads frequent heartburn (occurs 2 or more days a week) 1 to 4 days for full effect.</p> <p><b>Directions</b> For 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; so many people get complete relief of symptoms within 24 hours.</p> <p><b>14-Day Course of Treatment</b> Swallow 1 tablet with a glass of water before eating in the morning. 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. Swallow whole. Do not chew or crush tablets.</p> <p><b>Repeated 14-Day Courses (if needed)</b> You may repeat a 14-day course every 4 months. Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.</p> <p><b>Other information</b> Keep the carton it contains important information. Store at 20-25°C (68-77°F) and protect from moisture.</p> |
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**Omeprazole Delayed Release Tablets 20mg**

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



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**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**Bonus! 14 Free** NDC 00000-000-00



Treats **Frequent Heartburn!**  
Occurring **2 Or More Days a Week**

**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



28 ~~14~~ Tablets

Two ~~One~~ 14-day courses of treatment

(b) (4)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| <p><b>Drug Facts</b> (continued)</p> <p><b>Inactive ingredients</b> croscarmellose, ferric oxide red, ferric oxide yellow, hypromellose, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose acetate succinate, lactose monohydrate, magnesium stearate, polyethylene glycol, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate.</p> <p><b>Questions or comments?</b> 1-800-719-9280</p> |
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Manufactured by:  
**Deacel Pharma Technologies Ltd.**  
10 Hakdima Street, Yokneam, 20592, Israel

Made in Israel

: 91530 FA C893--0

CODE AREA

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Omeprazole Delayed Release Tablets 20mg

**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**28 Tablets (Bottle Carton)**



**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**FDA Approved**

**DIE CUT WINDOW**

**DIE CUT WINDOW**

Treats **Frequent Heartburn!**  
Occurring **2 Or More Days a Week**



**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



**28 Tablets**  
Two 14-day courses of treatment  
**2 BOTTLES INSIDE**

**Drug Facts**

**Active ingredient Purpose (in each tablet)**  
Omeprazole 20 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 omeprazole

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.
  - heartburn with **lightheadedness, sweating or dizziness**
  - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
  - frequent chest pain
  - frequent wheezing, particularly with heartburn
  - unexplained weight loss
  - nausea or vomiting ■ stomach pain ▶

**Drug Facts (continued)**

**Other information**

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

**Inactive ingredients**

camuaba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

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

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

Made in Israel  
Manufactured by:  
**Dexcel Pharma Technologies Ltd,**  
10 Hakidma Street, Yokneam, 20692, Israel

**Drug Facts (continued)**

Ask a doctor or pharmacist before use if you are taking

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

**Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

**If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**

- for 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, some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**

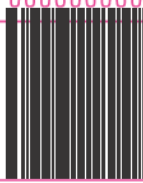
- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- swallow whole. Do not chew or crush tablets

**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
- children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition. ▶

**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**28 Tablets (Bottle Carton)**

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**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**Drug Facts (continued)**

- Ask a doctor or pharmacist before use if you are taking
- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
  - prescription antifungal or anti-yeast medicines
  - diazepam (anxiety medicine)
  - digoxin (heart medicine)
  - tacrolimus (immune system medicine)
  - prescription antiretrovirals (medicines for HIV infection)

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

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**

- for 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; some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**

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- 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
- swallow whole. Do not chew or crush tablets

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

**Drug Facts (continued)**

**Other information**

- read the directions and warnings before use
- Keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

**Inactive ingredients**

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

**Questions or comments?**

1-800-719-9260

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

Made in Israel

Manufactured by:  
**Dexcel Pharma Technologies Ltd.**  
10 Hakidma Street, Yokneam, 20692, Israel

**Bonus pack! 14 Free**

**DIE CUT WINDOW**

**DIE CUT WINDOW**

Treats Frequent Heartburn!  
Occurring 2 Or More Days a Week



**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



28 ~~14~~ Tablets  
Two ~~One~~ 14-day courses of treatment  
2 ~~1~~ BOTTLES INSIDE

NDC 0000-000-00

**Drug Facts**

**Active ingredient Purpose (in each tablet)**  
Omeprazole 20 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**

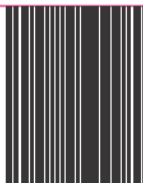
**Allergy alert:** Do not use if you are allergic to omeprazole

**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.

- 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



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LOT NO.

EXP.

: 915D6 FA CBB2-C

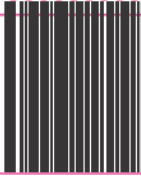
**CODE AREA**

(b) (4)

Proposed Draft Labeling  
NDA 22-032

Omeprazole Delayed Release Tablets, 20 mg  
28 Tablets (Bottle Carton)

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**Drug Facts (continued)**

Ask a doctor or pharmacist before use if you are taking

- warfarin, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

**Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea

If pregnant or breast-feeding, ask a health professional before use.  
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**

- for 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; some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**

- swallow 1 tablet with a glass of water before eating in the morning
- 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
- swallow whole. Do not chew or crush tablets

**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

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

**Drug Facts (continued)**

**Other information**

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

**Inactive ingredients**

carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

Questions or comments?  
1-800-719-9260

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

Made in Israel  
Manufactured by:  
Dexcel Pharma Technologies Ltd,  
10 Hakidma Street, Yokneam, 20692, Israel

**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**Bonus! 14 Free**

**DIE CUT WINDOW**

**DIE CUT WINDOW**

Treats **Frequent Heartburn!**  
Occurring **2 Or More Days a Week**



**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



28 ~~14~~ Tablets

Two ~~One~~ 14-day courses of treatment  
**2 BOTTLES INSIDE**

**Drug Facts**

**Active ingredient Purpose (in each tablet)**  
Omeprazole 20 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

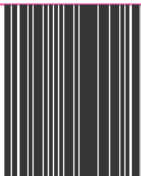
**Warnings**

**Allergy alert:** Do not use if you are allergic to omeprazole

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.
- 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



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LOT NO.

EXP.

: 915D6 FA CBB3-D

**CODE AREA**

(b) (4)



**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**42 Tablets**

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Drug Facts</b> (continued)</p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>your heartburn continues or worsens</li> <li>you need to take this product for more than 14 days</li> <li>you need to take more than 1 course of treatment every 4 months</li> <li>you get diarrhea</li> </ul> <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><b>Directions</b></p> <ul style="list-style-type: none"> <li>for adults 18 years of age and older</li> <li>this product is to be used once a day every 24 hours, every day for 14 days</li> <li>it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</li> </ul> <p><b>14-Day Course of Treatment</b></p> <ul style="list-style-type: none"> <li>swallow 1 tablet with a glass of water before eating in the morning</li> <li>take every day for 14 days</li> <li>do not take more than 1 tablet a day</li> <li>do not use for more than 14 days unless directed by your doctor</li> <li>swallow whole. Do not chew or crush tablets</li> </ul> <p><b>Repeated 14-Day Courses (if needed)</b></p> <ul style="list-style-type: none"> <li>you may repeat a 14-day course every 4 months</li> <li>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</li> </ul> <p>children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</p> | <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>read the directions and warnings before use</li> <li>keep the carton, it contains important information.</li> <li>store at 20-25°C (68-77°F) and protect from moisture</li> </ul> |
| <p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b>.....Acid reducer</p> <p>Omeprazole 20 mg</p> <p><b>Use</b></p> <ul style="list-style-type: none"> <li>treats frequent heartburn (occurs 2 or more days a week)</li> <li>not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul> <p><b>Warnings</b></p> <p><b>Do not use</b> if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>heartburn with lightheadedness, sweating or dizziness</li> <li>chest pain or shoulder pain with shortness of breath, sweating; pain spreading to arms, neck or shoulders; or tight headaches</li> <li>frequent chest pain</li> <li>unexplained weight loss</li> <li>nausea or vomiting</li> <li>stomach pain</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>warfarin, clopidogrel or citalopram (blood-thinning medicines)</li> <li>prescription antifungal or anti-yeast medicines</li> <li>diazepam (anxiety medicine)</li> <li>gabapentin (nerve pain medicine)</li> <li>esomeprazole (stomach medicine)</li> <li>prescription antiretrovirals (medicines for HIV infection)</li> </ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                          |



**Omeprazole Delayed Release Tablets 20mg**

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

**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**28 + 14 FREE**

NDC 00000-000-00



Treats **Frequent Heartburn!**  
Occurring **2 Or More Days a Week**

**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



**42 Tablets**  
Three 14-day courses of treatment

**Omeprazole Delayed Release Tablets 20mg**

**CODE AREA**

Manufactured by  
**Dexcel Pharma Technologies Ltd.**  
10 Haldimna Street, Yokneam, 20892, Israel

Made in Israel

91555 FA CB3-A

**Drug Facts** (continued)

**Inactive ingredients** carboxylic acid, ferric oxide red, ferric oxide yellow, hypromellose, hydroxyethylcellulose, lactose monohydrate, monothalamine, polyethylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, sodium stearoyl fumarate, talc, titanium dioxide, triethyl citrate

**(Questions or comments? 1-800-719-9280)**

(b) (4)



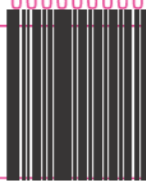






**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**42 Tablets (Bottle Carton)**

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**Drug Facts**

**Active ingredient (in each tablet)** Omeprazole 20 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 omeprazole  
 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.  
 ■ 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, clopidogrel or cilostazol (blood-thinning medicines)  
 ■ prescription antifungal or anti-yeast medicines  
 ■ diazepam (anxiety medicine)  
 ■ digoxin (heart medicine)  
 ■ tacrolimus (immune system medicine)  
 ■ prescription antiretrovirals (medicines for HIV infection)

**Drug Facts (continued)**

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

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**  
 ■ for 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; some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**  
 ■ swallow 1 tablet with a glass of water before eating in the morning  
 ■ 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  
 ■ swallow whole. Do not chew or crush tablets

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

**Other information**  
 ■ read the directions and warnings before use  
 ■ keep the carton, it contains important information.  
 ■ store at 20-25°C (68-77°F) and protect from moisture

**Drug Facts (continued)**

**Inactive ingredients**  
 carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate

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

Made in Israel  
 Manufactured by:  
 Dexcel Pharma Technologies Ltd.  
 10 Hakidma Street, Yokneam, 20692, Israel

**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**FDA Approved**

Treats **Frequent Heartburn!**  
 Occurring **2 Or More Days a Week**

**DIE CUT WINDOW**

**DIE CUT WINDOW**

**DIE CUT WINDOW**



**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



**42 Tablets**  
 Three 14-day courses of treatment  
**3 BOTTLES INSIDE**

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



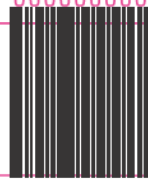
LOT NO.  
 EXP.  
 : 915D7 FA C8B1-B

**CODE AREA**

(b) (4)

**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**42 Tablets (Bottle Carton)**

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**Drug Facts**  
**Active ingredient (in each tablet)**  
 Omeprazole 20 mg.....Acid reducer  
**Purpose**  
 Acid reducer  
**Use**  
 ■ treats frequent heartburn (occurs **2 or more** days a week)  
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect  
**Warnings**  
**Allergy alert:** Do not use if you are allergic to omeprazole  
 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.  
 ■ 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, clopidogrel or cilostazol (blood-thinning medicines)  
 ■ prescription antifungal or anti-yeast medicines  
 ■ diazepam (anxiety medicine)  
 ■ digoxin (heart medicine)  
 ■ tacrolimus (immune system medicine)  
 ■ prescription antiretrovirals (medicines for HIV infection)

**Drug Facts (continued)**  
**Stop use and ask a doctor if**  
 ■ your heartburn continues or worsens  
 ■ you need to take this product for more than 14 days  
 ■ you need to take more than 1 course of treatment every 4 months  
 ■ you get diarrhea  
 if pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)  
**Directions**  
 ■ for 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; some people get complete relief of symptoms within 24 hours  
**14-Day Course of Treatment**  
 ■ swallow 1 tablet with a glass of water before eating in the morning  
 ■ 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  
 ■ swallow whole. Do not chew or crush tablets  
**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  
 ■ children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.  
**Other information**  
 ■ read the directions and warnings before use  
 ■ keep the carton. It contains important information.  
 ■ store at 20-25°C (68-77°F) and protect from moisture

**Drug Facts (continued)**  
**Inactive ingredients**  
 carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate  
**Questions or comments?**  
 1-800-719-9260

Made in Israel  
 Manufactured by:  
 Dexcel Pharma Technologies Ltd.  
 10 Hakidma Street, Yokneam, 20692, Israel

**Tips for Managing Heartburn**  
 ■ Do not lie flat or bend over after eating  
 ■ Do not wear tight-fitting clothing around the stomach  
 ■ Do not eat before bedtime  
 ■ Raise the head of your bed  
 ■ Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables  
 ■ Eat slowly and avoid big meals  
 ■ If overweight, lose weight  
 ■ Quit smoking

**Triple Pack** Three 14-day courses of treatment  
 Treats **Frequent Heartburn!**  
 Occurring **2 Or More Days a Week**

**DIE CUT WINDOW**

**DIE CUT WINDOW**

**DIE CUT WINDOW**



**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



**42 Tablets**  
 Three 14-day courses of treatment  
**3 BOTTLES INSIDE**

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



LOT NO.  
 EXP.  
 : 915D7 FA CBB2-A

**CODE AREA**



(b) (4)

**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**42 Tablets (Bottle Carton)**

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| <b>Drug Facts</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                | <b>Drug Facts (continued)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                       |
| <b>Active ingredient (in each tablet)</b><br>Omeprazole 20 mg.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Purpose</b><br>Acid reducer | <b>Stop use and ask a doctor if</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <ul style="list-style-type: none"> <li>your heartburn continues or worsens</li> <li>you need to take this product for more than 14 days</li> <li>you need to take more than 1 course of treatment every 4 months</li> <li>you get diarrhea</li> </ul> |
| <b>Use</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                | <b>Directions</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                       |
| <ul style="list-style-type: none"> <li>treats frequent heartburn (occurs <b>2 or more</b> days a week)</li> <li>not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                | <ul style="list-style-type: none"> <li>for adults 18 years of age and older</li> <li>this product is to be used once a day (every 24 hours), every day for 14 days</li> <li>it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                       |
| <b>Warnings</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                | <b>14-Day Course of Treatment</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                       |
| <p><b>Allergy alert:</b> Do not use if you are allergic to omeprazole</p> <p><b>Do not use</b> if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>heartburn with lightheadedness, sweating or dizziness</li> <li>chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>frequent chest pain</li> <li>frequent wheezing, particularly with heartburn</li> <li>unexplained weight loss</li> <li>nausea or vomiting</li> <li>stomach pain</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>warfarin, clopidogrel or cilostazol (blood-thinning medicines)</li> <li>prescription antifungal or anti-yeast medicines</li> <li>diazepam (anxiety medicine)</li> <li>digoxin (heart medicine)</li> <li>tacrolimus (immune system medicine)</li> <li>prescription antiretrovirals (medicines for HIV infection)</li> </ul> |                                | <ul style="list-style-type: none"> <li>swallow 1 tablet with a glass of water before eating in the morning</li> <li>take every day for 14 days</li> <li>do not take more than 1 tablet a day</li> <li>do not use for more than 14 days unless directed by your doctor</li> <li>swallow whole. Do not chew or crush tablets</li> </ul> <p><b>Repeated 14-Day Courses (if needed)</b></p> <ul style="list-style-type: none"> <li>you may repeat a 14-day course every 4 months</li> <li>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</li> <li>children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.</li> </ul> |                                                                                                                                                                                                                                                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                | <b>Other information</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                | <ul style="list-style-type: none"> <li>read the directions and warnings before use</li> <li>keep the carton. It contains important information.</li> <li>store at 20-25°C (68-77°F) and protect from moisture</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                       |

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| <b>Drug Facts (continued)</b>                                                                                                                                                                                                                                                                  |
| <b>Inactive ingredients</b>                                                                                                                                                                                                                                                                    |
| carnauba wax, ferric oxide red, ferric oxide yellow, hypromellose, hypromellose acetate succinate, lactose monohydrate, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide, triethyl citrate |
| <b>Questions or comments?</b>                                                                                                                                                                                                                                                                  |
| 1-800-719-9260                                                                                                                                                                                                                                                                                 |

Made in Israel  
 Manufactured by:  
 Dexcel Pharma Technologies Ltd.  
 10 Hakidma Street, Yokneam, 20692, Israel

**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**Bonus pack! 14 Free**

**Treats Frequent Heartburn!**  
 Occurring 2 Or More Days a Week

**DIE CUT WINDOW**

**DIE CUT WINDOW**

**DIE CUT WINDOW**



**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



**42 ~~28~~ Tablets**

Three ~~Two~~ 14-day courses of treatment  
**3 ~~2~~ BOTTLES INSIDE**

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



LOT NO.

**CODE AREA**

EXP.

: 915D7 FA CBB2-C

(b) (4)

**Proposed Draft Labeling**  
**NDA 22-032**  
**Omeprazole Delayed Release Tablets, 20 mg**  
**42 Tablets (Bottle Carton)**

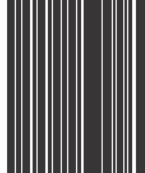
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| <b>Drug Facts</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                | <b>Drug Facts (continued)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                       |
| <b>Active ingredient (in each tablet)</b><br>Omeprazole 20 mg.....                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Purpose</b><br>Acid reducer | <b>Stop use and ask a doctor if</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <ul style="list-style-type: none"> <li>your heartburn continues or worsens</li> <li>you need to take this product for more than 14 days</li> <li>you need to take more than 1 course of treatment every 4 months</li> <li>you get diarrhea</li> </ul> |
| <b>Use</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                | <b>Directions</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                       |
| <ul style="list-style-type: none"> <li>treats frequent heartburn (occurs <b>2 or more</b> days a week)</li> <li>not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                | <ul style="list-style-type: none"> <li>for adults 18 years of age and older</li> <li>this product is to be used once a day (every 24 hours), every day for 14 days</li> <li>it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                       |
| <b>Warnings</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                | <b>14-Day Course of Treatment</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                       |
| <p><b>Allergy alert:</b> Do not use if you are allergic to omeprazole</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><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>heartburn with <b>lightheadedness, sweating or dizziness</b></li> <li>chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li><b>frequent chest pain</b></li> <li>frequent wheezing, particularly with heartburn</li> <li>unexplained weight loss</li> <li>nausea or vomiting</li> <li>stomach pain</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>warfarin, clopidogrel or cilostazol (blood-thinning medicines)</li> <li>prescription antifungal or anti-yeast medicines</li> <li>diazepam (anxiety medicine)</li> <li>digoxin (heart medicine)</li> <li>tacrolimus (immune system medicine)</li> <li>prescription antiretrovirals (medicines for HIV infection)</li> </ul> |                                | <ul style="list-style-type: none"> <li>swallow 1 tablet with a glass of water before eating in the morning</li> <li>take every day for 14 days</li> <li>do not take more than 1 tablet a day</li> <li>do not use for more than 14 days unless directed by your doctor</li> <li>swallow whole. Do not chew or crush tablets</li> </ul> <p><b>Repeated 14-Day Courses (if needed)</b></p> <ul style="list-style-type: none"> <li>you may repeat a 14-day course every 4 months</li> <li>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>read the directions and warnings before use</li> <li>keep the carton. It contains important information.</li> <li>store at 20-25°C (68-77°F) and protect from moisture</li> </ul> |                                                                                                                                                                                                                                                       |
| <b>Questions or comments?</b><br>1-800-719-9260                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                | <b>Other information</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                       |
| <p>Made in Israel</p> <p>Manufactured by:<br/>                 Dexcel Pharma Technologies Ltd.,<br/>                 10 Hakidma Street, Yokneam, 20692, Israel</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                | <p>Read the directions and warnings before use.</p> <p>Keep the carton. It contains important information.</p> <p>Store at 20-25°C (68-77°F) and protect from moisture.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                       |

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**Tips for Managing Heartburn**

- Do not lie flat or bend over after eating
- Do not wear tight-fitting clothing around the stomach
- Do not eat before bedtime
- Raise the head of your bed
- Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables
- Eat slowly and avoid big meals
- If overweight, lose weight
- Quit smoking

**Bonus! 14 Free**

Treats **Frequent Heartburn!**  
 Occurring **2 Or More Days a Week**

**DIE CUT WINDOW**

**DIE CUT WINDOW**

**DIE CUT WINDOW**



**Omeprazole Delayed Release Tablets 20mg**

**Acid Reducer**



**42 ~~28~~ Tablets**

Three ~~Two~~ 14-day courses of treatment  
**3 ~~2~~ BOTTLES INSIDE**

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



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LOT NO.

EXP.

: 91507 FA C883-D

**CODE AREA**

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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THERESA M MICHELE  
08/16/2013