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

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)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretroviralis (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.

Drug Facts (continued)

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

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

0 00000 00000 0

Omeprazole Delayed Release Tablets 20mg

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

FDA Approved

NDC 00000-000-00

TreatMy Heartburn .com

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

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

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

Made in Israel

CODE AREA

: 91574 FA CBB1

(b) (4)

2-14-13

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

Made in Israel

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

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

FDA Approved

NDC 0000-000-00

DIE CUT WINDOW

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

TreatMy Heartburn .com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

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

0 00000 00000 0

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)

2-14-13

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)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiviral drugs (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

Omeprazole Delayed Release Tablets 20mg

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

0 00000 00000 0

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

14 FREE

NDC 00000-000-00

TreatMyHeartburn.com

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

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

Made in Israel

CODE AREA

: 91530 FA CB3

Omeprazole Delayed Release Tablets 20mg

(b) (4)

2-14-13

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

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, dopidogrel 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. Incase 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
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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

Omeprazole Delayed Release Tablets 20mg

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

0 00000 00000 0

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

NDC 00000-000-00

TreatMy Heartburn .com

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

CODE AREA

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

Made in Israel

:91530 FA CBB1-B

Omeprazole Delayed Release Tablets 20mg

(b) (4)

2-14-13

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

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, dopidogrel 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

Omeprazole Delayed Release Tablets 20mg

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

0 00000 00000 0

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

NDC 00000-000-00

TreatMy Heartburn .com

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

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

Made in Israel

CODE AREA

:91530 FA CB82-C

Omeprazole Delayed Release Tablets 20mg

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

(b) (4)

4-29-13

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)
- 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. Incase 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

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

Omeprazole Delayed Release Tablets 20mg

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

0 00000 00000 0

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

TreatMyHeartburn.com

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

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

Made in Israel

CODE AREA

:91530 FA C883-D

Omeprazole Delayed Release Tablets 20mg

(b) (4)

7-8-13

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

FDA Approved

NDC 0000-0000-00

DIE CUT WINDOW

DIE CUT WINDOW

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

TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

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

0 00000 00000 0

LOT NO.

EXP.

CODE AREA

: 9151D6 FA CBB1-B

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 ▶

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(b) (4)

2-14-13

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

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 pack! 14 Free

NDC 0000-0000-00

DIE CUT WINDOW

DIE CUT WINDOW

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

TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

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

LOT NO.

EXP.

CODE AREA

: 9151D6 FA CBB2-C

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 ▶

(b) (4)

4-29-13

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

(b) (4)

7-8-13

2-14-13

(b) (4)

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

Omeprazole Delayed Release Tablets 20 mg

Acid Reducer

42 Tablets
Three 14-day courses of treatment

Omeprazole Delayed Release Tablets 20 mg

14 FREE

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

TreatMy Heartburn .com

NDC 00000-000-00

Omeprazole Delayed Release Tablets 20 mg

0 00000 00000 0

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

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
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- 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 ▼

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

Made in Israel

CODE AREA

: 91555 FA CB3_B

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

2-14-13

(b) (4)

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

Omeprazole Delayed Release Tablets 20mg

42 Tablets
Three 14-day courses of treatment

Acid Reducer

Omeprazole Delayed Release Tablets 20mg

TreatMyHeartburn.com

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

28 + 14 FREE

NDC 00000-000-00

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

Made in Israel

CODE AREA

: 91555 FA CB3-A

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

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)
- 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
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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.

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 ▼

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

2-14-13

(b) (4)

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

Omeprazole Delayed Release Tablets 20mg

42 Tablets

Three 14-day courses of treatment

Acid Reducer

Omeprazole Delayed Release Tablets 20mg

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

TreatMyHeartburn.com

FDA Approved

NDC 00000-000-00

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

Made in Israel

CODE AREA

: 71555 FA CBB1-B

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

Omeprazole Delayed Release Tablets 20mg

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)
- 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

▼

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

4-29-13

(b) (4)

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

Omeprazole Delayed Release Tablets 20mg

42 Tablets
Three 14-day courses of treatment

Acid Reducer

Omeprazole Delayed Release Tablets 20mg

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

TreatMyHeartburn.com

***Triple Pack** Three 14-day courses of treatment*

NDC 00000-000-00

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

Made in Israel

CODE AREA

1555 FA C882-A

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

Omeprazole Delayed Release Tablets 20mg

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

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)
- 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)

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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.
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▼

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

4-29-13

(b) (4)

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 ~~28~~ Tablets

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

Bonus pack! 14 Free

NDC 00000-000-00

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

TreatMy Heartburn .com

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

Omeprazole Delayed Release Tablets 20mg

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

Made in Israel

CODE AREA

: 91555 FA CBB2-C

Drug Facts

Active ingredient (in each tablet) — **Purpose**
Omeprazole 20 mg ..... Acid reducer

Use
- treats frequent heartburn (occurs ***2 or more*** days a week)
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- 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)
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- diazepam (anxiety medicine)
- digoxin (heart medicine)
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- 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
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If pregnant or breast-feeding, ask a health professional before use.

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Repeated 14-Day Courses (if needed)
- you may repeat a 14-day course every 4 months
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Other information
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- keep the carton. It contains important information.
- store at 20-25°C (68-77°F) and protect from moisture

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

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

Drug Facts

Active ingredient (in each tablet) — **Purpose**

Omeprazole 20 mg ..... Acid reducer

Use

- treats frequent heartburn (occurs *2 or more* days a week)
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Warnings

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

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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
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Other information

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

Omeprazole Delayed Release Tablets 20mg

0 00000 00000 0

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

Bonus! 14 Free

NDC 00000-000-00

TreatMy Heartburn .com

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

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 ~~28~~ Tablets
Three ~~Two~~ 14-day courses of treatment

Omeprazole Delayed Release Tablets 20mg

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

Made in Israel

CODE AREA

: 91555 FA CBB3-D

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

(b) (4)

7-8-13

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

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)
- 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**

NDC 0000-000-00

DIE CUT WINDOW | DIE CUT WINDOW | DIE CUT WINDOW

TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

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

0 00000 00000 0

LOT NO.

EXP.

:915D7 FA CBB1-B

CODE AREA

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

(b) (4)

2-14-13

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

Drug Facts

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- 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)

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Other information
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Drug Facts (continued)

Inactive ingredients
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- 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**

NDC 0000-000-00

TreatMyHeartburn.com

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Acid Reducer

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

0 00000 00000 0

LOT NO.

CODE AREA

EXP.

:915D7 FA CBB2-A

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

(b) (4)

4-29-13

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

Drug Facts

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Omeprazole 20 mg ..... Acid reducer

Use
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- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

Drug Facts (continued)

Stop use and ask a doctor if
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- you need to take this product for more than 14 days
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Bonus pack! 14 Free

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

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-0000-00

TreatMyHeartburn.com

Omeprazole Delayed Release Tablets 20mg

Acid Reducer

20

42 ~~28~~ Tablets

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

3 ~~2~~ BOTTLES INSIDE

0 00000 00000 0

LOT NO.

EXP.

:91507 FA CBB2-C

CODE AREA

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

(b) (4)

4-29-13

Proposed Draft Labeling
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Drug Facts (continued)

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

DIE CUT WINDOW

DIE CUT WINDOW

DIE CUT WINDOW

NDC 0000-0000-00

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Omeprazole Delayed Release Tablets 20mg

Acid Reducer

42 ~~28~~ Tablets

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3 ~~2~~ BOTTLES INSIDE

0 00000 00000 0

LOT NO.

EXP.

:915D7 FA CBB3-D

CODE AREA

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

(b) (4)

7-8-13

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

/s/

THERESA M MICHELE
08/16/2013