

**OMEPRAZOLE DELAYED RELEASE- omeprazole tablet, delayed release  
Weeks & Leo Co., Inc.**

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**Omeprazole Delayed Release Tablets, 20 mg**

**Active Ingredient (In each tablet)**

Omeprazole delayed-release tablet, 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.

- 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 or 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 or clopidogrel (blood-thinning medicine)
- 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**

- side effects occur. You may report side effects to FDA at **1-800-FDA-1088**
- 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

**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.

**Directions**

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

**14-Day Course of Treatment**

- 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 chew or crush the tablets
- do not crush tablets in food
- do not use for more than 14 days unless directed by your doctor

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

**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

**Tamper-evident:**

do not use if any blister unit is torn, broken, or shows any signs of tampering.

**Carton Label - 14 tablets**

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

Omeprazole  
delayed release tablets 20 mg  
acid reducer

**14 TABLETS**

One 14-day course of treatment

Compare to Prilosec\* OTC active ingredient only

Pharmacist Recommended



14 tablet box front

## Drug Facts

### Active ingredient (in each tablet)

Omeprazole delayed-release tablet, 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 or clopidogrel (blood-thinning medicine) ■ 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** ■ side effects occur. You may report side effects to FDA at 1-800-FDA-1088 ■ 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

**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.

### Directions

■ adults 18 years of age and older

■ this product is to be used once a day (every 24 hours), every day for 14 days

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

#### 14-Day Course of Treatment

■ 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 chew or crush the tablets ■ do not crush tablets in food ■ do not use for more than 14 days unless directed by your doctor

#### 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.

14 tablet box rear

## Blister Label

### Omeprazole DR Tablets

20 mg

Acid reducer

**Push tablet through foil.**

Dexcel Ltd.

1 Dexcel St. Or Akiva

30600, Israel

**Do not chew or crush tablets**

**Do not crush tablets in food**



## Patient Package Insert

### Omeprazole Delayed Release Tablets 20 mg

#### Acid Reducer

**Please read all of this package insert before taking Omeprazole Delayed Release Tablets 20 mg. Save this to read, as you need.**

#### How Omeprazole Delayed Release Tablets 20 mg Work For Your Frequent Heartburn

Omeprazole Delayed Release Tablets 20 mg work differently from other heartburn products, such as antacids and other acid reducers. Omeprazole Delayed Release Tablets 20 mg stop acid production at the source - the **acid pump** that produces stomach acid. Omeprazole Delayed Release Tablets 20 mg are to be used once a day (every 24 hours), every day for 14 days.

#### What to Expect When Using Omeprazole Delayed Release Tablets 20 mg

Omeprazole Delayed Release Tablets 20 mg are a different type of medicine from antacids and other acid reducers. Omeprazole Delayed Release Tablets 20 mg may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours. Make sure you take the entire 14 days of dosing to treat your frequent heartburn.

#### Safety Record

For years, doctors have prescribed omeprazole to treat acid-related conditions in millions of people safely.

#### Who Should Take Omeprazole Delayed Release Tablets 20 mg

This product is for adults (18 years and older) with **frequent heartburn** - when you have heartburn 2 or more days a week.

- Omeprazole Delayed Release Tablets 20 mg are **not** intended for those who have heartburn infrequently, one episode of heartburn a week or less, or for those who want immediate relief of heartburn.

#### How to Take Omeprazole Delayed Release Tablets 20 mg

## 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 chew or crush the tablets.
- Do not crush tablets in food.
- Do not use for more than 14 days unless directed by your doctor.

It is important not to chew or crush these tablets, or crush the tablets in food. This decreases how well Omeprazole Delayed Release Tablets 20 mg work.

## When to Take Omeprazole Delayed Release Tablets 20 mg Again

**You may repeat a 14-day course of therapy every 4 months.**

## When to Talk to Your Doctor

Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

## Warnings and When to Ask Your Doctor

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

- clopidogrel bisulfate (anti-blood clotting medicine)
- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- atazanavir (medicine 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

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

**Keep out of reach of children.**

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

Tips for Managing Heartburn

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

How are Omeprazole Delayed Release Tablets 20 mg Sold

Omeprazole Delayed Release Tablets 20 mg are available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes contain one, two and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

For Questions or Comments About Omeprazole Delayed Release Tablets 20 mg

Call **1-800-719-9260**

Made in Israel

Manufactured by:  
**DEXCEL® LTD.**  
Southern Industrial Zone  
Or Akiva 30600, Israel

<b>OMEPRAZOLE DELAYED RELEASE</b>			
omeprazole tablet, delayed release			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11383-257(NDC:64861-303)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

## Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
HYPROMELLOSE ACETATE SUCCINATE 12070923 (3 MM2/S) (UNII: 36BGF0E889)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

## Product Characteristics

Color	BROWN (brownish)	Score	no score
Shape	OVAL (capsule-shaped)	Size	13mm
Flavor		Imprint Code	20
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11383-257-61	2 in 1 CARTON		
1		14 in 1 BLISTER PACK		
2	NDC:11383-257-16	1 in 1 CARTON		
2		14 in 1 BLISTER PACK		
3	NDC:11383-257-43	3 in 1 CARTON		
3		14 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022032	07/12/2011	

**Labeler** - Weeks & Leo Co., Inc. (005290028)

## Establishment

Name	Address	ID/FEI	Business Operations
Weeks & Leo Co., Inc.		005290028	REPACK(11383-257, 11383-257)

