OMEPRAZOLE - omeprazole tablet, delayed release
Sun Pharmaceutical Industries, Inc.

Omeprazole Delayed-release Tablets, 20 mg

Active ingredient(in each tablet)

Omeprazole USP 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
- 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**

These may be signs of a serious condition. See your doctor.

Ask a docotor befor use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are

taking a prescription drug. Acid reducers may interact with certain prescription drugs.

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
- you develop a rash or joint pain

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 to 25° C (68 to 77° F) and protect from moisture

Inactive ingredients

anhydrous lactose, hypromellose, hypromellose acetate succinate, iron oxide red, iron oxide yellow, lactose monohydrate, methyl cellulose, monoethanolamine, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, sodium stearate, sodium stearyl fumarate, talc, titanium dioxide and triethyl citrate.

The imprinting ink contains ammonium hydroxide, black iron oxide, n-butyl alcohol, propylene glycol and shellac.

Questions or Comments?

Call toll free 1-800-818-4555 weekdays.

Tips of 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

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 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.

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.

- Children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition.
- 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 or 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 use for more than 14 days unless directed by your doctor
- Swallow whole. Do not chew or crush tablets.

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
- 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

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.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

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
- you develop a rash or joint pain

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 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

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 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 toll free 1-800-818-4555 weekdays.

Distributed by:

Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512

Manufactured by:

Sun Pharmaceutical Industries Limited

Survey No. 259/15,

Dadra-396 191, (U.T. of D & NH), India.

PGPI0356

ISS. 04/2019

Principal Display Panel - Foil

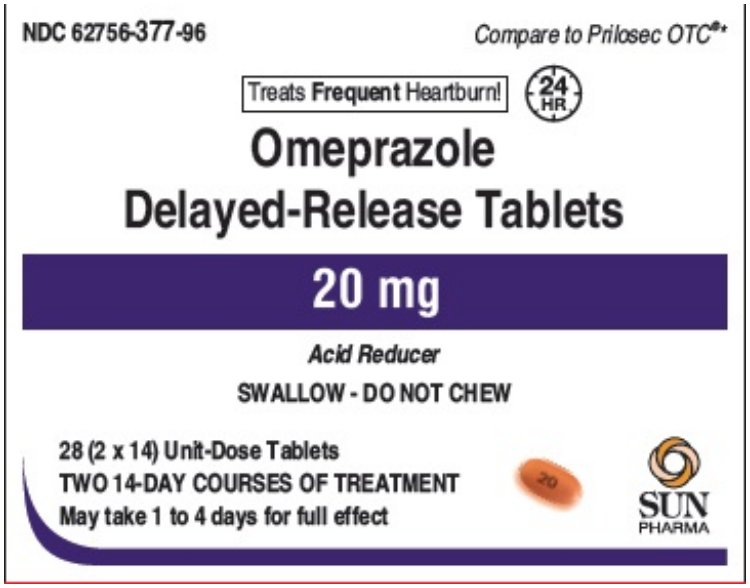
62756-377-40
Omeprazole Delayed-release Tablet
20 mg
Acid reducer
PUSH THROUGH
Mfg. by: **Sun Pharmaceutical Ind Ltd**., India.
Dist. by: **Sun Pharmaceutical Ind Inc**., NJ 08512
PGPF0520

Principal Display Panel - Blister Carton

NDC 62756-377-96
Compare to Prilosec OTC ® *
Treats **Frequent** Heartburn! **(24 HR)**

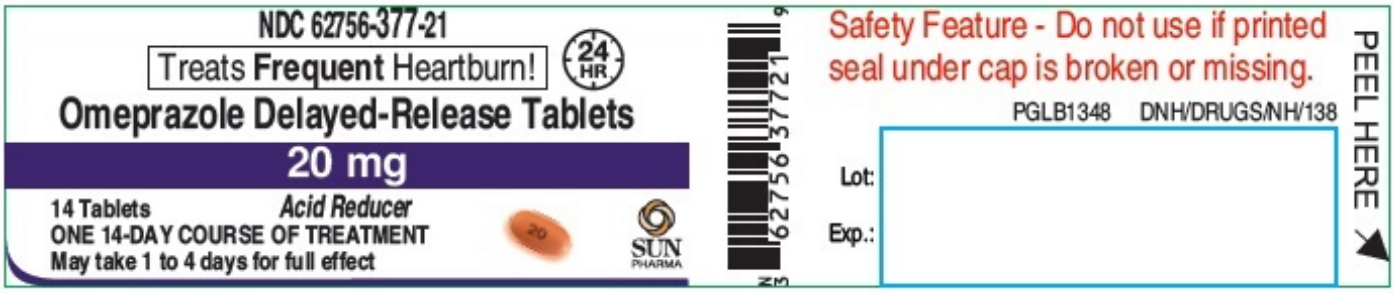
Compare to Prilosec OTC ® *
Omeprazole Delayed-release Tablets
20 mg
Acid Reducer

SWALLOW - DO NOT CHEW
28 (2 x 14) Unit-Dose Tablets
TWO 14-DAY COURSES OF TREATMENT
May take 1 to 4 days for full effect



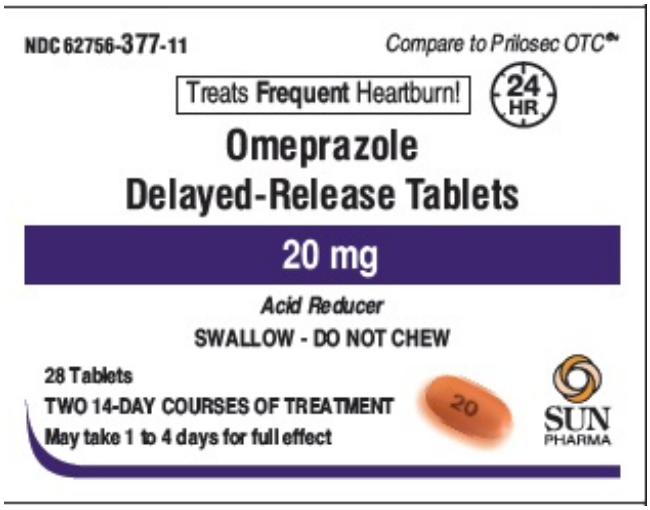
Principal Display Panel - Label

NDC 62756-377-21
Treats**Frequent**Heartburn! **(24 HR)**
Omeprazole Delayed-release Tablets
20 mg
Acid Reducer
14 Tablets
ONE 14-DAY COURSE OF TREATMENT
May take 1 to 4 days for full effect



Principal Display Panel - Bottle Carton

NDC 62756-377-11
Compare to Prilosec OTC ® *
Treats **Frequent** Heartburn**! (24 HR)**
Omeprazole Delayed-release Tablets
20 mg
Acid Reducer
SWALLOW - DO NOT CHEW
28 Tablets
TWO 14-DAY COURSES OF TREATMENT
May take 1 to 4 days for full effect



OMEPRAZOLE

omeprazole tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62756-377
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9)	OMEPRAZOLE	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYPROMELLOSE ACETATE SUCCINATE 12070923 (3 MM2/S) (UNII: 36BGF0E889)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
METHYLCELLULOSE (1500 MPA.S) (UNII: P0NTE48364)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
AMMONIA (UNII: 5138Q19F1X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	

SHELLAC (UNII: 46N107B71O)	

Product Characteristics			
Color	BROWN (brownish pink)	**Score**	no score
Shape	OVAL (biconvex)	**Size**	12mm
Flavor		**Imprint Code**	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62756-377-21	1 in 1 CARTON	01/01/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:62756-377-11	2 in 1 CARTON	01/01/2019	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:62756-377-12	3 in 1 CARTON	01/01/2019	
3		14 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:62756-377-70	1 in 1 CARTON	01/01/2019	
4		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:62756-377-96	2 in 1 CARTON	01/01/2019	
5		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:62756-377-79	3 in 1 CARTON	01/01/2019	
6		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207891	01/01/2019	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(62756-377) , MANUFACTURE(62756-377)

Revised: 4/2019 Sun Pharmaceutical Industries, Inc.