OMEPRAZOLE- omeprazole tablet, delayed release
Thirty Madison Inc

Omeprazole Delayed Release Tablets

Active Ingredient (in each tablet)

Omeprazole USP, 20mg

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 SECTION

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 beofre using if you are

taking:

• warfarin, clopidogrel or cilostazol (blood thinning medications)

• prescription antifungal or anti-yeast medicines

• diazepam (anxiety medicine)

• digoxin (heart medicine)

• tacrolimus or mycophenolate mofetil (immune system medicines)

• prescription antiretrovirals (medicines for HIV infection)

• methotrexate (arthritis medicine)

Stop use and ask a doctor if:

•your heartburn continues or worsens

•you need to take this product for more than 14 days

•you need to take more than 1 course of treatement 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 (1800-222-1222)

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 relief of symptoms within 24 hours

• **14 day course of treatment**

•swallow 1 tablet with a glass of water befre 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 days 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

ammonia solution, ammonium hydroxide, carnauba wax, hypromellose acetate succinate, hypromellose, iron oxide black, lactose monohydrate, monoethanolamine, n-butyl alcohol, polyethylene glycol, polyvinyl alcohol, povidone, propylene glycol, red iron oxide, sodium stearate, sodium starch glycolate, shellac glaze, sodium lauryl sulphate, sodium stearyl fumarate, talc, titanim dioxide, triethyl citrate, yellow iron oxide

Questions or comments?

call 1-888-375-3784

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

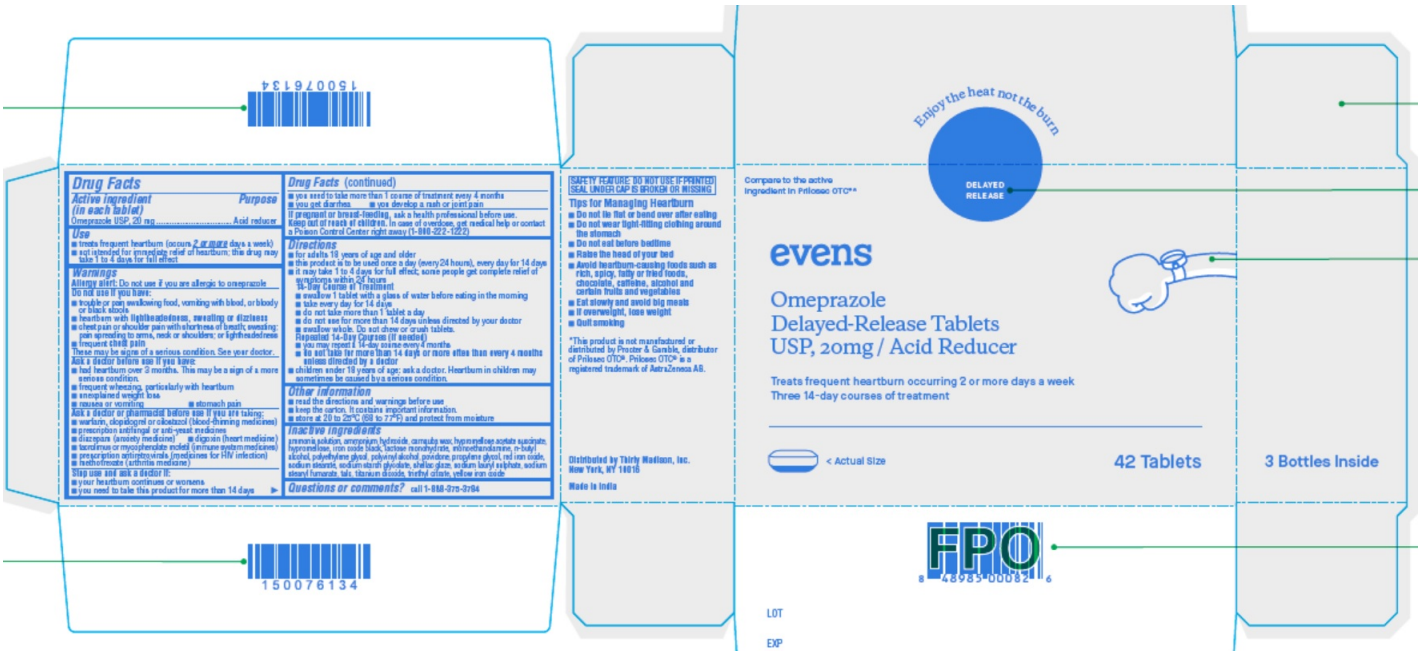
• Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol and certain fruits and vegetables

• Eat slowly and avoid big meals

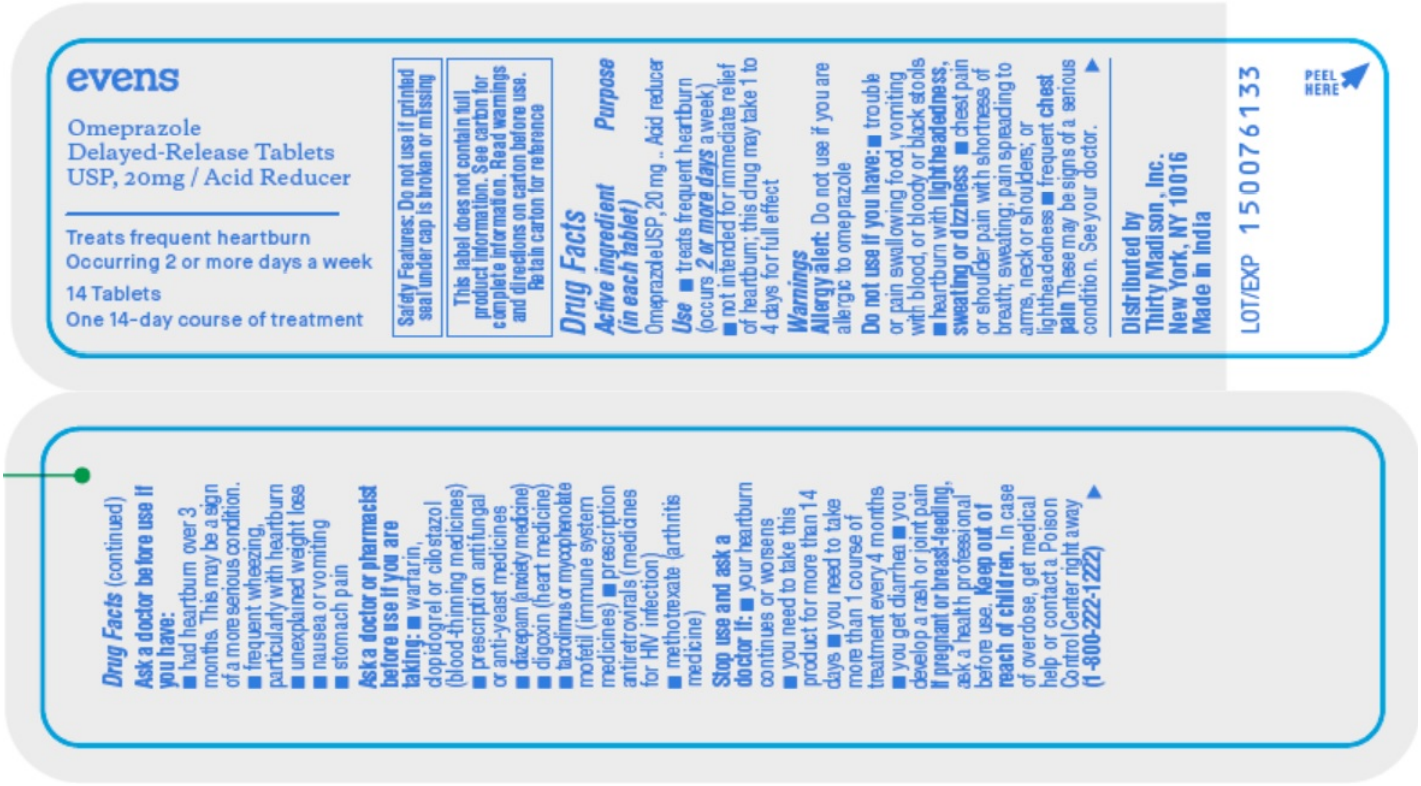
• If overweight, lose weight

• Quit smoking

Carton label



Bottle Label



OMEPRAZOLE

omeprazole tablet, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71713-201
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**
AMMONIA (UNII: 5138Q19F1X)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
HYPROMELLOSE ACETATE SUCCINATE 06081224 (3 MM2/S) (UNII: 6N003M473W)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
Polyethylene Glycol 3350 (UNII: G2M7P15E5P)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	BROWN (brownish pink)	**Score**	no score
Shape	CAPSULE	**Size**	12mm
Flavor		**Imprint Code**	O20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71713-201-01	1 in 1 CARTON	05/31/2019	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:71713-201-03	3 in 1 CARTON	05/31/2019	
2		14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207740	05/31/2019	

Labeler - Thirty Madison Inc (080774087)

Establishment

Name	Address	ID/FEI	Business Operations
Dr.Reddy's Laboratories Limited (SEZ UNIT)		860037244	analysis(71713-201) , manufacture(71713-201)

Establishment

Name	Address	ID/FEI	Business Operations
Reed Lane Inc		001819879	repack(71713-201)

Revised: 3/2019 Thirty Madison Inc