OMEPRAZOLE- omeprazole tablet, delayed release Padagis Israel Pharmaceuticals Ltd

Perrigo Omeprazole Drug Facts

Active ingredient (in each tablet)

Omeprazole 20 mg

Purpose

Acid reducer

Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

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

Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- 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).

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

Principal Display Panel

Compare to Prilosec OTC®

Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

28 Tablets

Actual Size

24HR

Two 14-day courses of treatment

May take 1 to 4 days for full effect

Treats Frequent Heartburn!

See current Drug Facts

Allegan, MI 490 To www.p.e.ngo.com Perrigo. Ag pangaga les nie bet M

10 Hakidma Street, Yokun eam 206 92 00, Israel btJ saigolonnbaTemied9 labxa0 www.mac.rn.eqph:

Clue stions or comments? 1-80 0-7 19-92 60

02-888-2085- \$

This product is not manufact uned or distributed by Procter & Gamble, distributor of Prhosec OTC

- myouneed to take more of the at treatment every 4 m on the myouder dian hea. myoudevelop a markon joint pain
 - Tyourheartbum continues orwersers

 younsed to take trisproduct formore than 14 days
 - Stop u seand ask a doctor ift

Ask a doctor orp harm acist be fore use if you are taking apresciption drug. Acidreducesm ay in teract with certain prescription drugs.

- ms accuracy of an

- Ask a doctor beforeu seif you have: Mhad hearbu m over3 months. This maybea sign of am ore serbus
- mhearthurmvith lighthee deln eas sweating or dizziness

 "Echa Spin ior drouder pain with altor tree of beath; sweating; pain

 spin eding to ame, neck or aboulders; orlightheed choes s

 "I sequent cheat p ain

 "I sequent cheat b ain

 "I sequent cheat b air securition. Seeyour doctor.
- Do not use ifyou he se: It you'd not book not book not book not book or blood you sloot should the second of the s

Allergy alert: Do not use if you are alergic to omegazake

.....gm O Səlozs 1qəmO Active ingredient (in each tablet)

gurd La cts

■read the directions and warnings before use ■keep the carton, it contains in podant information. ■s to read 20-2 6°C (6 8-17°F) and protect from moisture

n di Asmin of ni 19 Aft O

вошедшее р осупаа руд авгрия сондирои: #children under 18 years of age:aska doctor. Hearrburnin da ldrenm ay

Repea fed 14-Day Courses (freeded)

Byounn a sprepact a 14-day couseway Arn on miss

Mat on Dribas formore the not 14 day sor more of ten fra nevery

A mon fraun lessed irected by a doctor

draby hypomestics, and the advance sections of the managed properties and the section of the sec

In 3c II ve Ingredients armana hericoxide ekiconies, be recipied way a serie

■swallowwhole Donotcheworcash tablets

■do not use form ore than 1 4 days unless die atedby your doctor mswalow 1 tablet with a glasc of water before eating in free morning mt ace every day for 14 days mdo not taken or ethan 1 tablet a day

14-Day Course of Treatment

m for at ute 18 years of ageand older m fire producties be be used one as day (every 24 hours), every day for 14 day m from y take 1 bak days forful effect, some peoplegat complete ellef of symptoms within 24 hours

lf pregnanto rbrea at-feeding, ask absalth porte atonalbefore use. Keep out of reach of child as n, h casa of overlose, get medical helpor contacta. Poison ControlCenter tj htaway (1-8 00-222 - 1222).

Drug Fac ts (con tinued)

NDC 45802-888-30

Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

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

Perrigo[®]

NDC 45802-888-30

Omeprazole

Delayed Release Tablets 20 mg **Acid Reducer**

28 Tablets

Two 14-day courses of treatment May take 1 to 4 days for full effect

See current Drug Facts



Omeprazole Delayed Release Tablets 20 mg Acid Reducer

91530RTC12

Compare to Prilosec OTC®*



NDC 45802-888-30

SAFETY FEATURE - DO NOT US IF PRINTED TABLET BLISTER Unit is open or torn.

OMEPRAZOLE

omeprazole tablet, delayed release

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:45802-888

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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 87.960XD6UM)	

Product Characteristics

Color	BROWN	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-888- 55	3 in 1 CARTON	11/06/2008	
1		14 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
_	NDC:45802-888-	2 :~ 1 CADTON	02/25/2000	

4	30	Z III I CARTON	02/25/2000	
2		14 in 1 CARTON		
2		1 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
NDA	NDA022032	02/25/2008	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 11/2021 Padagis Israel Pharmaceuticals Ltd