

OMEPRAZOLE- omeprazole tablet, delayed release
Padagis Israel Pharmaceuticals Ltd

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.
- omeprazole may cause severe skin reactions. Symptoms may include:
 - skin reddening
 - blisters
 - rash

If an allergic reaction occurs, stop use and seek medical help right away.

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?

Principal Display Panel

Compare to Prilosec OTC[®]

Omeprazole Delayed Release Tablets 20 mg

Acid Reducer

Actual Size

24HR

42 Tablets

Three 14-day courses of treatment

May take 1 to 4 days for full effect

Treats Frequent Heartburn!

Padagis[®]

NDC 45802-888-55

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



NDC 45802-888-55

Compare to Prilosec OTC^{®*}

Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

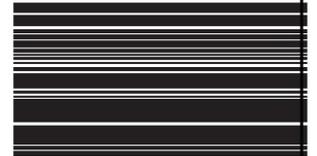
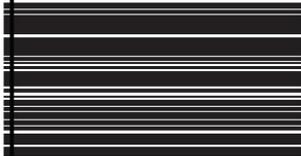
42 Tablets

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

Actual Size



Treats Frequent Heartburn!



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NDC 45802-888-55

Delayed Release Tablets 20 mg

Omeprazole

Acid Reducer

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Omeprazole 20 mg Acid reducer</p> <p>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.</p> <p>Warnings</p> <p>Allergy alert: ■ do not use if you are allergic to omeprazole. ■ omeprazole may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>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.</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.</p> <p>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</p>	<p>Drug Facts (continued)</p> <p>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).</p> <p>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</p> <p>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.</p> <p>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.</p> <p>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</p> <p>Inactive ingredients camauba 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</p> <p>Questions or comments? 1-800-719-9260</p>
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NDC 45802-888-55

Omeprazole

Delayed Release Tablets 20 mg

Acid Reducer

Scratch Feature - Do not use if perforated tablet blister until to open or torn.

This product is not manufactured or distributed by Procter & Gamble, distributor of Pribsec OTC.

 **Padagis.**

Manufactured for Padagis® by Dexcel Pharma Technologies Ltd
10 Hakidma Street, Yokneam 2069200, Israel
www.padagis.com

Made in Israel



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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)	
HYPROMELLOSE ACETATE SUCCINATE, UNSPECIFIED (UNII: A7ZHS2R34)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

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		
2	NDC:45802-888-30	2 in 1 CARTON	02/25/2008	
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: 2/2025

Padagis Israel Pharmaceuticals Ltd