GOOD SENSE OMEPRAZOLE- omeprazole tablet, orally disintegrating, delayed release L. Perrigo Company

Perrigo Omeprazole Delayed Release Orally Disintegrating Tablets 20 mg 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 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

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- 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
- do not take this medicine with alcohol

Repeated 14-Day Course (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 before use. 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); keep product out of high heat and moisture

Inactive ingredients

amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate,

sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

Questions or comments?

1-800-719-9260: weekdays 7:30 AM to 5:00 PM EST

Package/Label Principal Display Panel

 $MELTech^{^{TM}}$

Melts In Your Mouth

Treats Frequent Heartburn!

24 HR

Omeprazole

Delayed Release Orally Disintegrating Tablets 20 mg

Actual Size

Strawberry Flavor

Acid Reducer

Melts in Your Mouth

Dissolves Without Water

42 Tablets

Three 14-Day Courses of Treatment

May Take 1 to 4 Days For Full Effect

Compare to Prilosec OTC®





Delayed Release Orally Disintegrating Tablets 20 mg

GOODSENSE.

Acid Reducer

GOODSENSE.

MELTech[™]

Treats Frequent Heartburn!

24 HR

Omeprazo

Delayed Release Orally Disintegrating Tablets 20 mg

Acid Reducer

42 Tablets

Three 14-Day Courses of Treatment May Take 1 to 4 Days For Full Effect

Strawberry Flavor

Melts in Your Mouth Dissolves Without Water

Compare to Prilosec OTC®*

Drug Facts

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24 HR) Omeprazole

DelayedRekaseOrally Disintegrating Tablets 20 mg

Acid Reducer

Tips for Managing Heartburn ■ Donot le fist or bendover after eating ■ Donot wear tight-fitting ciothing around the stomach ■ Donot act before be dtime

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"This product is not manufactured or distributed by Prooter & Gamble, distributor of Priloseo OFOS).

MADE IN ISRAEL

Distributed By Perrigo® Allegan, MI 49010

Acid Reducer

GOOD SENSE OMEPRAZOLE

omeprazole tablet, orally disintegrating, delayed release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0113-0520
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
DIMETHYLAMINO ETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960 MK)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	RED (reddish)	Score	no score
Shape	ROUND	Size	9 mm
Flavor	STRAWBERRY	Imprint Code	20
Contains			

F	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-0520-55	3 in 1 CARTON	06/21/2018	
1		14 in 1 CARTON		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2 NDC:0113-0520-74	14 in 1 CARTON	06/19/2018	
2	$1\ \mbox{in}\ 1\ \mbox{BLISTER}$ PACK; Type 0: Not a Combination Product		
Marketing Inf	ormation		
Marketing Inf		Marketing Start Date	Marketing End Date
	y Application Number or Monograph Citation	Marketing Start Date 06/19/2018	Marketing End Date

Labeler - L. Perrigo Company (006013346)

Revised: 4/2019 L. Perrigo Company