

**OMESEC - omeprazole capsule, delayed release**  
**Corporacion Infarmasa**

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**Drug Facts**

Ask a doctor before use if you have:

- \* Had heartburn over 3 months. This may be a sign of a more serious condition.
- \* 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.
- \* Frequent wheezing, particularly with heartburn
- \* Unexplained weight loss
- \* Nausea or vomiting
- \* Stomach pain

Ask a doctor or pharmacist before use if you are taking:

- Warfarin (blood-thinning medicine)
- Prescription antifungal or anti-yeast medicines
- Diazepam (anxiety medicine)
- Digoxin (heart medicine)
- Tacrolimus (immune system medicine)
- Atazanavir (medicine for HIV infection)

**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.

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

Do not use if capsule blister unit is open or torn

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

If pregnant or breast-feeding, ask a health professional before use

**Stop use and ask a doctor if** an allergic reaction to this product occurs. Seek medical help right away.

Stop use and ask a Doctor if:

- \* Your heartburn continues or worsens
- \* You need to take his product for more than 14 days
- \* You need to take more than 1 course of treatment every 4 months

Do not use if capsule blister unit is open or torn

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.

If you have questions of a medical nature, please contact your pharmacist, doctor or health care professional

- Read the directions, warnings and package insert before use
- Keep the carton and package insert. They contain important information
- Store at 20°C to 25°C ( 68°F to 77°F)
- Keep product out of high heat and humidity
- Protect product from moisture

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, although some people get complete relief of symptoms within 24 hours

#### 14-Day Course of Treatment

- Swallow 1 capsule with a glass of water before eating in the morning
- Take every day for 14 days
- Do not take more than 1 capsule a day
- Do not chew or crush the capsule
- Do not crush capsules in food
- Do not use for more than 14 days unless directed by your doctor

#### Repeated 14-Day Courses (if needed)

- You may repeat a 14-day course every 4 months
- **Do not take more than 14 days or more often than every 4 month unless directed by a doctor**

Children under 18 years of age: ask a doctor

#### **Other Information**

- Read the directions, warnings and package insert before use

Diethyl Phthalate, Sodium Lauryl Sulfate, Disodium Phosphate, Hydroxypropyl Cellulose, Lactose, Hypromellose, Corn Starch, Hypromellose Phthalate, Sucrose

Omesec Caps

24 x 115 x 90

Lot #:  
Expiration Date:

**Drug Facts**

<b>Active Ingredient</b>	Acid reducer
<b>Purpose</b>	Omeprazole delayed-release capsules, 20 mg

**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. 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.
- 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.
- Frequent wheezing, particularly with heartburn.
- Unexplained weight loss.
- Nausea or vomiting.
- Stomach pain.

**Ask a doctor or pharmacist before use if you are taking**

- Warfarin (blood-thinning medicine)

**Directions**

- 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, although 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 crush tablets in food.
- Do not chew or crush the tablets.
- Do not use for more than 14 days unless directed by your doctor.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**If pregnant or breast-feeding,** ask a health professional before use.

**Stop use and ask a doctor if**

- Heartburn continues or worsens.
- You need to take this product for more than 14 days.
- Your heartburn continues or worsens.

**Other information**

- Children under 18 years of age, ask a doctor.
- Read the directions, warnings and package insert before use.

**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.**

**Other information**

- Read the directions, warnings and package insert before use.

- Keep the carton and package insert. They contain important information.
- Store at 20-25 °C (68-77 °F).
- Keep product out of high heat and humidity.
- Protect product from moisture.

**Inactive ingredients:** diethyl phthalate, sodium lauryl sulfate, disodium phosphate, hydroxypropyl cellulose, lactose, hypromellose, corn starch, hypromellose phthalate, sucrose.

OmeSec  
28 capsules

# OmeSec

Treats Frequent Heartburn occurring 2 or More days a week

**OTC** OMEPRAZOLE delayed-release capsules  
20 mg / acid reducer

**28 capsules**  
Two 14-day courses of treatment

Manufactured by Corporation Infarmasa S.A. Lima, Peru

Exclusive Distributor Global Corporation Inc. 621 N.W. 53rd. St., Suite 240, Boca Raton, Florida 33487

Questions or comments? 561 338 5221

# OMESEC

omeprazole capsule, delayed release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:16853-1308
<b>Route of Administration</b>	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
DIETHYL PHTHALATE (UNII: UF064M00AF)	0.144 mg
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	0.432 mg
SODIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: 94255I6E2T)	0.816 mg
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	6.24 mg
LACTOSE (UNII: J2B2A4N98G)	8.16 mg
HYPROMELLOSE (UNII: 3NXW29V3WO)	11.81 mg
STARCH, CORN (UNII: O8232NY3SJ)	24.96 mg
HYPROMELLOSE PHTHALATE (31% PHTHALATE, 170 CST) (UNII: 8LDD2V82F5)	25.18 mg
SUCROSE (UNII: C15IH8M554)	142.26 mg

## Product Characteristics

<b>Color</b>	red (Red Capsule)	<b>Score</b>	score with uneven pieces
<b>Shape</b>	CAPSULE (Delayed Release Capsules)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	None
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16853-1308-2	28 in 1 BLISTER PACK		
2	NDC:16853-1308-1	14 in 1 BLISTER PACK		
3	NDC:16853-1308-3	42 in 1 BLISTER PACK		
4	NDC:16853-1308-4	2 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075410	02/28/2010	

**Labeler** - Corporacion Infarmasa (934098294)

**Establishment**

Name	Address	ID/FEI	Business Operations
Corporacion Infarmasa		934098294	manufacture

Revised: 2/2010

Corporacion Infarmasa