

**OMEPRAZOLE 20 MG - omeprazole 20 mg tablet, delayed release**  
**MARKSANS PHARMA LIMITED**

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**Omeprazole Delayed Release Tablets 20 mg**

**ACTIVE INGREDIENT(S)**

***Active ingredient (in each tablet)***

Omeprazole, USP 20 mg  
(equivalent to 20.6 mg omeprazole magnesium)

**PURPOSE**

***Purpose***

Acid reducer

**USE(S)**

***Uses***

- 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**

***Warnings***

**Allergy alert:**

- Do not use if you are allergic to Omeprazole
- Omeprazole may cause severe skin reactions. Symptoms include:
  - skin reddening
  - blisters
  - rashIf an allergic reaction occurs, stop use and seek medical attention right away.

**DO NOT USE**

**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**

### **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**

**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 DOCTOR IF**

### **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

## **PREGNANCY/BREASTFEEDING**

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

## **KEEP OUT OF REACH OF CHILDREN**

**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**

## ***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.

## **STORAGE**

### ***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**

### ***Inactive ingredients***

colloidal silicone dioxide, croscopovidone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 6000, polysorbate 80, red iron oxide, simethicone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

## **QUESTIONS OR COMMENTS**

***Questions or comments?*** Call **1-877-376-4271** (weekdays 9 AM to 5 PM)

### **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 do not eat big meals.
- If overweight, lose weight.
- Quit smoking.

Manufactured for:

**Time-Cap Labs, Inc.**

7 Michael Avenue,  
Farmingdale,  
NY 11735, USA

Manufactured by:

**Marksans Pharma Ltd.**

Plot No. L-82, L-83  
Verna Indl. Estate  
Verna, Goa-403722, India

## **PRINCIPAL DISPLAY PANEL**

NDC: 25000-091-76

Omeprazole Delayed-Release Tablets 20 mg

14's count Carton

Varnish Omit

Lot No.:  
Exp Date:



Manufactured for: Time-Cap-Labs, Inc.  
7 Michael Avenue, Farmingdale, NY 11735, USA  
Manufactured by: Marksans Pharma Ltd.  
Plot No. L-82, L-83, Verna Ind. Estate, Verna, Goa-403722, India  
Mfg. Lic. No. 500/DRUGS/515 R11123  
This product is not manufactured or distributed by  
Procter & Gamble, distributor of Prilosec OTC®

### Drug Facts

**Active ingredient**  
(in each tablet)  
Omeprazole, USP 20 mg  
(equivalent to 20.0 mg  
omeprazole magnesium)..... Acid reducer

### Purpose

**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 include:  
■ skin redness ■ 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.

### Drug Facts (continued)

#### 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**

### Tips for Managing Heartburn

■ Do not eat before bedtime  
■ Do not wear tight-fitting clothing around the stomach  
■ 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  
**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

### Drug Facts (continued)

■ 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

colloidal silicon dioxide, croscopolone, glycerol monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 6000, polysorbate 80, red iron oxide, simethicone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

### Questions or comments?

Call 1-877-376-4271 (weekdays 9 AM to 5 PM)



See Current Drug Facts

**Omeprazole** Delayed-Release Tablets **20 mg**

**Acid Reducer**

Treats **Frequent** Heartburn!

**14** Tablets

One 14-day course of treatment  
May take 1 to 4 days for full effect



ACTUAL SIZE

Varnish/Print Omit Area

Varnish  
Omit

Varnish  
Omit

NDC: 25000-091-76  
Omeprazole Delayed-Release Tablets 20 mg  
14's count Label

### Drug Facts (continued)

**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** colloidal silicon dioxide, croscopolone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 6000, polysorbate 80, red iron oxide, simethicone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

### Questions or comments?

Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

Manufactured for:  
**Time-Cap-Labs, Inc.**  
7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by:  
**Marksans Pharma Ltd.**  
Plot No. L-82, L-83, Verna Indl. Estate,  
Verna, Goa-403722, India  
Mfg. Lic. No.: GO/DRUGS/515  
R11123

Adhesive Area

### Drug Facts (continued)

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).

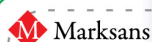
### Directions

- 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

Varnish Omit Area

Lot No.:  
Exp Date:

PEEL HERE



NDC 25000-091-76

See Current Drug Facts

**Omeprazole**  
Delayed-Release Tablets

20 mg

**Acid Reducer**

Treats Frequent Heartburn!

**14 Tablets**

One 14-day course of treatment  
May take 1 to 4 days for full effect

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

### Drug Facts

**Active ingredient (in each tablet)**

Omeprazole, USP 20 mg  
(equivalent to 9.00 mg omeprazole magnesium)

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 redness
  - 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

NDC: 25000-091-77

Omeprazole Delayed-Release Tablets 20 mg  
14's count (2 x 7's blister) Carton



See Current Drug Facts

# Omeprazole Delayed-Release Tablets 20 mg

**Acid Reducer**

Treats **Frequent Heartburn!**

**THIS PACKAGE FOR HOUSEHOLDS  
WITHOUT YOUNG CHILDREN**

**14 Tablets**

One 14-day course of treatment  
May take 1 to 4 days for full effect



ACTUAL SIZE

NDC 25000-091-77  
Compare to the active ingredient in Prilosec OTC<sup>®</sup>

## Drug Facts

**Active ingredient (in each tablet) Purpose**

Omeprazole, USP 20 mg (equivalent to 20.6 mg omeprazole magnesium).....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

**Drug Facts** (continued)



**Drug Facts** (continued)

## Warnings

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Symptoms include:  
■ skin reddening  
■ blisters  
■ rash  
If an allergic reaction occurs, stop use and seek medical help right away.

**Do not use if you have:**  
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■ chest pain or shoulder pain with shortness of breath; sweating, pain spreading to arms, neck or shoulders; or lightheadedness  
These may be signs of a serious condition. See your doctor.

**Ask a doctor before use if you have:**  
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■ stomach pain

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**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

**Drug Facts** (continued)

**Inactive ingredients** colloidal silicon dioxide, croscavellone, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol 400, polyethylene glycol 6000, polyborate 80, red iron oxide, simethicone,

**Drug Facts** (continued)

■ you develop a rash or joint pain  
■ you get diarrhea  
4 months

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  
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**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

**Drug Facts** (continued)

sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

## Questions or comments?

Call 1-877-376-4271 (weekdays 9 AM to 5 PM)  
[Do not use if blistered unit is torn or broken]

### 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

Lot No.:

Exp Date:

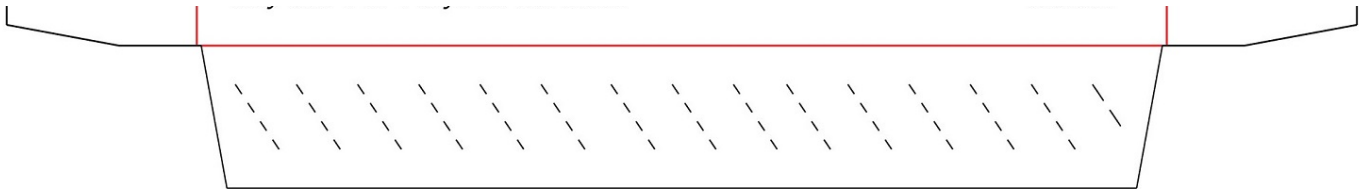
Mfg. Lic. No.: G00DRUGS/515 R11123



Manufactured for: Time-Cap-Labs, Inc.  
7 Michael Avenue, Farmingdale, NY 11735, USA

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Plot No. L-82, L-83, Verna Indl. Estate,  
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\*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC<sup>®</sup>



OMEPRAZOLE 20 MG

omeprazole 20 mg tablet, delayed release

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:25000-091 |
| Route of Administration | ORAL           |                    |               |

| Active Ingredient/Active Moiety  |  |                   |
|--|--|-------------------|
| Ingredient Name  |  | Basis of Strength |
| OMEPRAZOLE MAGNESIUM (UNII: 426QFE7XLK) (OMEPRAZOLE - UNII:KG60484QX9) |  | OMEPRAZOLE        |
|  |  | 20 mg             |

| Inactive Ingredients   |          |
|--|----------|
| Ingredient Name  | Strength |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)                         |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                               |          |
| CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)                      |          |
| HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)          |          |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)                     |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)                            |          |
| METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J) |          |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)                    |          |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)                       |          |
| POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)                      |          |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H)                                |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                              |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                                   |          |
| SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)                       |          |
| STARCH, CORN (UNII: O8232NY3SJ)                                  |          |
| SUCROSE (UNII: C151H8M554)                                       |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                              |          |
| TRIETHYL CITRATE (UNII: 8Z96QXD6UM)                              |          |

| Product Characteristics |      |       |          |
|-------------------------|------|-------|----------|
| Color                   | PINK | Score | no score |
| Shape                   | OVAL | Size  | 14mm     |

|                       |                  |  |                      |                    |
|-----------------------|------------------|--|----------------------|--------------------|
| Flavor                |                  | Imprint Code   |                      | 91                 |
| Contains              |                  |  |                      |                    |
|                       |                  |  |                      |                    |
| Packaging             |                  |  |                      |                    |
| #                     | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
| 1                     | NDC:25000-091-77 | 2 in 1 CARTON  | 08/12/2025           |                    |
| 1                     |                  | 7 in 1 BLISTER PACK; Type 0: Not a Combination Product |                      |                    |
| 2                     | NDC:25000-091-76 | 1 in 1 CARTON  | 08/12/2025           |                    |
| 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                  |                  | ANDA218829   | 08/12/2025           |                    |
|                       |                  |  |                      |                    |

**Labeler -**
MARKSANS PHARMA LIMITED (925822975)

| <b>Establishment</b>    |         |           |                        |
|-------------------------|---------|-----------|------------------------|
| Name                    | Address | ID/FEI    | Business Operations    |
| MARKSANS PHARMA LIMITED |         | 925822975 | MANUFACTURE(25000-091) |