**TOPCARE OMEPRAZOLE- omeprazole tablet, delayed release**
**Topco Associates LLC**

---

**Topco Associates LLC. Omeprazole Delayed Release Tablets 20 mg Drug Facts**

**Active ingredient (in each tablet)**

Omeprazole 20 mg

**Purpose**

Acid reducer

**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**

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, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection)

**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

**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?**

1-888-423-0139

**Principal Display Panel**

TABLETS

Omeprazole DELAYED RELEASE TABLETS 20 mg

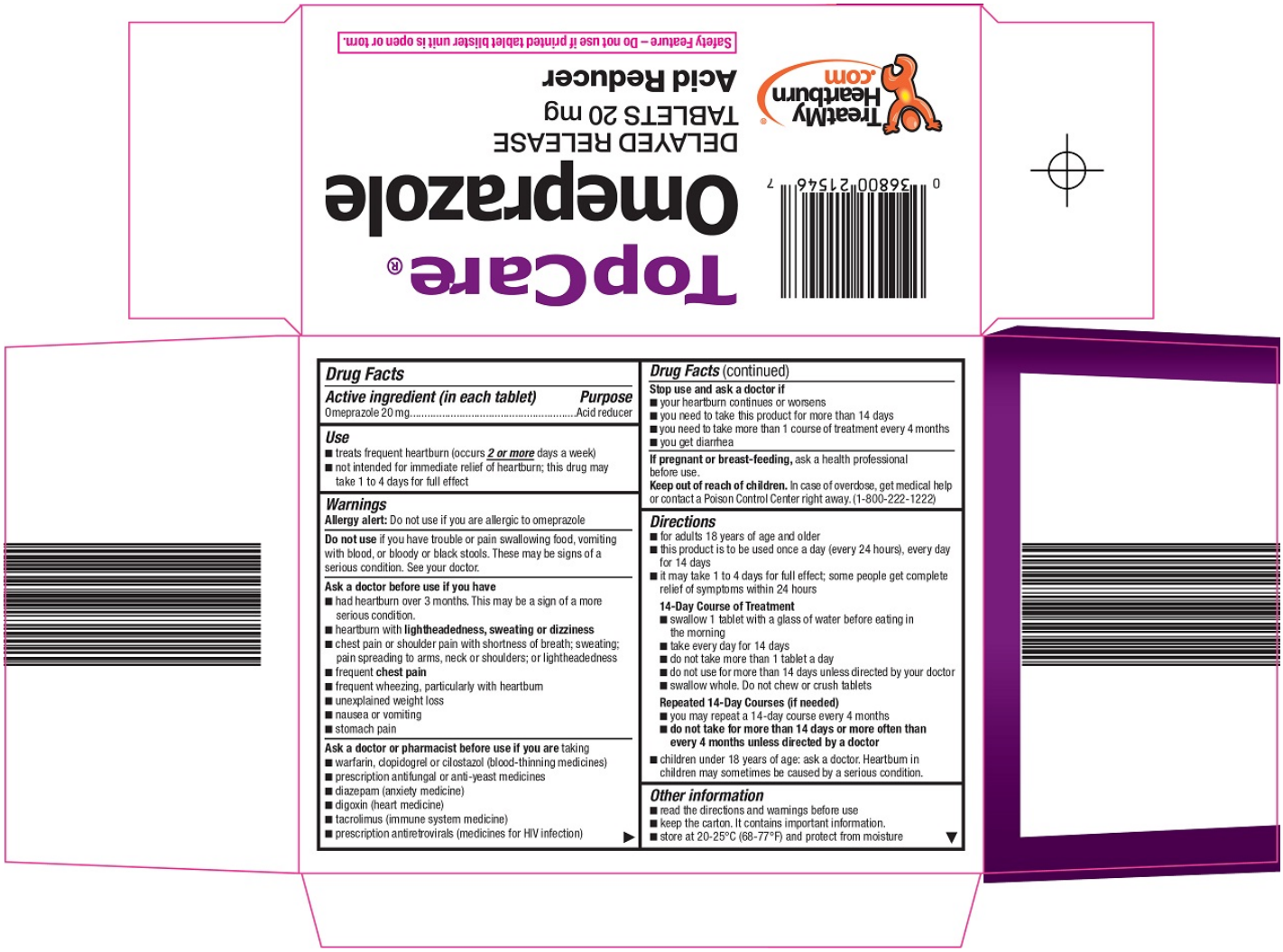
Acid Reducer

Treats Frequent Heartburn!

Occurring 2 Or More Days A Week

actual size

# 14-day course of treatment {Replace the # of 14-day course of treatment with the # in the package}



TopCare®

Omeprazole

DELAYED RELEASE
TABLETS 20 mg
Acid Reducer

Safety Feature – Do not use if printed tablet blister unit is open or torn.

TreatMyHeartburn.com

0 36800 21546 7

**Drug Facts**

**Active ingredient (in each tablet)** **Purpose**
Omeprazole 20 mg.....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. 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, clopidogrel or cilostazol (blood-thinning medicines)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)
- tacrolimus (immune system medicine)
- prescription antiretrovirals (medicines for HIV infection) ▶

**Drug Facts** (continued)

**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

**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 ▼

# TOPCARE OMEPRAZOLE

omeprazole tablet, delayed release

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG LABEL | **Item Code (Source)** | NDC:36800-915 |
| **Route of Administration** | ORAL | **DEA Schedule** | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **OMEPRAZOLE** (OMEPRAZOLE) | OMEPRAZOLE | 20 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CARNAUBA WAX** | |
| **FERRIC OXIDE RED** | |
| **FERRIC OXIDE YELLOW** | |
| **HYPROMELLOSES** | |
| **LACTOSE MONOHYDRATE** | |

| | |
|---|---|
| **PROPYLENE GLYCOL** | |
| **SODIUM LAURYL SULFATE** | |
| **SODIUM STEARATE** | |
| **SODIUM STEARYL FUMARATE** | |
| **TALC** | |
| **TITANIUM DIOXIDE** | |
| **TRIETHYL CITRATE** | |
| **MONOETHANOLAMINE** | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | BROWN | **Score** | no score |
| **Shape** | OVAL | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | 20 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:36800-915-74 | 1 in 1 CARTON | | |
| **1** | | 14 in 1 BLISTER PACK | | |
| **2** | NDC:36800-915-30 | 2 in 1 CARTON | | |
| **2** | | 1 in 1 CARTON | | |
| **2** | | 14 in 1 BLISTER PACK | | |
| **3** | NDC:36800-915-55 | 3 in 1 CARTON | | |
| **3** | | 1 in 1 CARTON | | |
| **3** | | 14 in 1 BLISTER PACK | | |
| **4** | NDC:36800-915-03 | 3 in 1 CARTON | | |
| **4** | | 14 in 1 BOTTLE | | |
| **5** | NDC:36800-915-01 | 1 in 1 CARTON | | |
| **5** | | 14 in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| NDA | NDA022032 | 02/29/2008 | |

## Labeler - Topco Associates LLC (006935977)

Revised: 2/2013 Topco Associates LLC