

# GRAYCARY

1625 Massachusetts Avenue NW, Suite 300  
Washington, DC 20036-2247  
drosen@graycary.com  
www.graycary.com

O] 202-238-7749  
F] 202-238-7701

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## VIA FEDERAL EXPRESS

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

## ANDA SUITABILITY PETITION

Gray Cary Ware & Freidenrich LLP submits this ANDA Suitability Petition under the provisions of § 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.93 requesting that the Commissioner of Food and Drugs allow the submission and the filing of an Abbreviated New Drug Application ("ANDA") for Omeprazole Magnesium Delayed Release Capsules, Eq. to 20mg base for over-the-counter ("OTC") use as discussed below.

### A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs permit the submission and filing of an ANDA for Omeprazole Magnesium Delayed Release Capsules, Eq. to 20mg base pursuant to § 505 (j)(2)(C) of the Federal Food, Drug and Cosmetic Act. Currently, Omeprazole Magnesium is available OTC in Delayed Release Tablets, Eq. to 20mg base under AstraZeneca's approved NDA and is marketed under the trade name Prilosec OTC™. The change requested in this Suitability Petition is a change in dosage form; from a delayed release tablet to a delayed release capsule. AstraZeneca has previously addressed pediatric requirements for the drug product. The publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") notes that AstraZeneca's Prilosec™ NDA's addressed pediatric issues for this chemical entity.

### B. Statement of Grounds

1. As noted above, the current reference listed drug, AstraZeneca's Prilosec OTC™, NDA 21-229 is marketed as a delayed release tablet. The change requested in this Suitability Petition is a change in dosage form; from a delayed release tablet to a delayed release capsule.

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2. The change in dosage form, from a delayed release tablet to a delayed release capsule is clearly authorized under the ANDA Suitability Petition process, 21 § 505 (j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.93.
3. The ANDA applicant will include in the ANDA both *in vitro* dissolution profile data and *in vivo* bioavailability data comparing the reference listed drug Prilosec OTC™ Omeprazole Magnesium Delayed Release Tablets Eq. to 20mg base to the proposed ANDA product Omeprazole Magnesium Delayed Release Capsules, Eq. to 20mg base.
4. AstraZeneca has addressed pediatric requirements for the drug product. The Orange Book notes that AstraZeneca's NDA's for Prilosec™ have addressed pediatric issues for chemical entity.
5. Labeling for the product will be identical to the enclosed labeling for Prilosec OTC™ aside from differences due to a different manufacturer and different dosage form.

**C. Environmental Impact**

The Petitioner claims a categorical exclusion under 21 CFR § 25.24.

**D. Economic Impact**

By allowing the submission and filing of an ANDA for Omeprazole Delayed Release Capsules, Eq. to 20mg base the public will be afforded access to a lower priced, OTC alternative delayed-release dosage form for Omeprazole Magnesium.

**E. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views of which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Sincerely yours,

A handwritten signature in black ink that reads "David L. Rosen" followed by "by NAB". The signature is written in a cursive, somewhat stylized script.

David L. Rosen, B.S. Pharm, J.D.

Attachment (Labeling)

# Prilosec

## OTC™

Omeprazole magnesium delayed-release  
tablet 20.6 mg (equivalent to  
20 mg omeprazole)  
Acid reducer

Please read all of this package insert  
before taking Prilosec OTC™.  
Save this to read, as you need.

### How Prilosec OTC Works For Your Frequent Heartburn

Prilosec OTC works differently from other OTC heartburn products, such as antacids and other acid reducers. Prilosec OTC stops acid production at the source – the **acid pump** that produces stomach acid. Prilosec OTC is to be used once a day (every 24 hours), every day for 14 days.

### What to Expect When Using Prilosec OTC

Prilosec OTC is a different type of medicine from antacids and other acid reducers. Prilosec OTC may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours. Make sure you take the entire 14 days of dosing to treat your frequent heartburn.

### Safety Record

For years, doctors have prescribed Prilosec to treat acid-related conditions in millions of people safely.

### Who Should Take Prilosec OTC

This product is for adults (18 years and older) with **frequent heartburn**—

when you have heartburn 2 or more days a week.

- Prilosec OTC is **not** intended for those who have heartburn infrequently, one episode of heartburn a week or less, or for those who want immediate relief of heartburn.

### How to Take Prilosec OTC

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

It is important not to chew or crush these tablets, or crush the tablets in food. This decreases how well Prilosec OTC works.

#### When to Take Prilosec OTC Again

You may repeat a 14-day course of therapy every 4 months.

#### When to Talk to Your Doctor

Do not take for more than 14 days or more often than every 4 months unless directed by a doctor.

### Warnings and When to Ask Your Doctor

**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
- 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)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)

**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

**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.

### Tips for Managing Heartburn

- Do not lie flat or bend over soon after eating.
- Do not eat late at night or just before bedtime.
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some fruits and vegetables.
- Eat slowly and do not eat big meals.
- If you are overweight, lose weight.
- If you smoke, quit smoking.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.

### How is Prilosec OTC Sold

Prilosec OTC is available in 14 tablet, 28 tablet and 42 tablet sizes. These sizes contain one, two, and three 14-day courses of treatment, respectively. Do not use for more than 14 days in a row unless directed by your doctor. For the 28 count (two 14-day courses) and the 42 count (three 14-day courses), you may repeat a 14-day course every 4 months.

### For Questions or Comments About Prilosec OTC

Call 1-800-289-9181

<p><b>Drug Facts</b></p>	<p><b>Drug Facts</b> (continued)</p>
<p><b>Active ingredient (in each tablet)</b> Omeprazole magnesium delayed-release tablet 20.6 mg (equivalent to 20 mg omeprazole).....Acid reducer</p>	<p><b>Purpose</b> <b>Use</b>  <ul style="list-style-type: none"> <li>■ treats frequent heartburn (occurs <b>2 or more</b> days a week)</li> <li>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul> </p>
<p><b>Warnings</b> <b>Allergy alert:</b> Do not use if you are allergic to omeprazole</p> <p><b>Do not use</b> if you have</p> <ul style="list-style-type: none"> <li>■ trouble or pain swallowing food</li> <li>■ vomiting with blood</li> <li>■ bloody or black stools</li> </ul> <p>These may be signs of a serious condition. See your doctor.</p>	<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ adults 18 years of age and older</li> <li>■ this product is to be used once a day (every 24 hours), every day for 14 days</li> <li>■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</li> </ul>
<p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>■ heartburn with <b>lightheadedness, sweating or dizziness</b></li> <li>■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>■ frequent <b>chest pain</b></li> <li>■ frequent wheezing, particularly with heartburn</li> <li>■ unexplained weight loss</li> <li>■ nausea or vomiting</li> <li>■ stomach pain</li> </ul>	<p><b>14-Day Course of Treatment</b></p> <ul style="list-style-type: none"> <li>■ swallow 1 tablet with a glass of water before eating in the morning</li> <li>■ take every day for 14 days</li> <li>■ do not take more than 1 tablet a day</li> <li>■ do not chew or crush the tablets</li> <li>■ do not crush tablets in food</li> <li>■ do not use for more than 14 days unless directed by your doctor</li> </ul> <p><b>Repeated 14-Day Courses (if needed)</b></p> <ul style="list-style-type: none"> <li>■ you may repeat a 14-day course every 4 months</li> <li>■ <b>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</b></li> <li>■ children under 18 years of age: ask a doctor</li> </ul>
<p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>■ warfarin (blood-thinning medicine)</li> <li>■ prescription antifungal or anti-yeast medicines</li> <li>■ diazepam (anxiety medicine)    ■ digoxin (heart medicine)</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ your heartburn continues or worsens</li> <li>■ you need to take this product for more than 14 days</li> <li>■ you need to take more than 1 course of treatment every 4 months</li> </ul>	<p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ read the directions, warnings and package insert before use</li> <li>■ keep the carton and package insert. They contain important information.</li> <li>■ store at 20-25°C (68-77°F)</li> <li>■ keep product out of high heat and humidity</li> <li>■ protect product from moisture</li> </ul> <p><b>Inactive ingredients</b> glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate</p> <p><b>Questions? 1-800-759-4841</b></p>