

IP1

**Omeprazole Magnesium  
for  
Over-The-Counter (OTC) Use**

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**NDA 21-229  
AstraZeneca, LP/ Procter & Gamble Co.**

IP2

**Douglas Ws. Bierer, Ph.D.**

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**Director, Regulatory Affairs  
Worldwide Personal Health Care  
Procter & Gamble**

## **NDA Indications and Dose**

- ◆ **NDA Indications:**
  - Relief of heartburn, acid indigestion and sour stomach
  - Prevention of heartburn, acid indigestion and sour stomach
  
- ◆ **Doses Studied:**
  - 10 and 20 mg Omeprazole as Omeprazole magnesium

## **Omeprazole Marketing History**

- ◆ **Omeprazole: Rx**
  - Marketed for more than 12 years
  - Approved for 8 indications
  - Doses range from 20 to 80 mg
  
- ◆ **Omeprazole magnesium: OTC**
  - 10 and 20 mg switched OTC for treatment of heartburn (Sweden, 1999)
  
- ◆ **Worldwide Use**
  - Available in 107 countries
  - 380 million patient treatments

**Clinical and  
Consumer Research Program**

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IP 5

- ◆ Clinical Studies:  
11,600 people with heartburn
- ◆ Consumer Studies:  
13,000 people with heartburn

**Evolution of  
OTC Heartburn Management**

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IP 6

- ◆ Antacids — symptom relief
- ◆ H<sub>2</sub>RAs — symptom relief  
+ prevention of meal-induced heartburn
- ◆ Omeprazole — symptom relief  
+ 24 hour prevention

## **Many Consumers Have Heartburn More Than Once Per Week**

IP7

- ◆ 40% of US adults experience heartburn
- ◆ 46% heartburn occurs once per week or more
- ◆ For OTC H<sub>2</sub>RA users, the frequency is 2.4 times/week
- ◆ 58% OTC H<sub>2</sub>RA users suffer from heartburn on consecutive days

## **How Consumers Manage Heartburn**

IP8

- ◆ Medications used to manage heartburn
  - 77% use OTC medications
  - 19% use prescription drugs
- ◆ OTC product use
  - 80% Antacid
  - 64% H<sub>2</sub>RA
- ◆ OTC medications are used for relief and prevention
  - 26% of OTC H<sub>2</sub>RA users treat preventatively

**Consumers Consult Physicians  
And Pharmacists About Their Heartburn**

IP 9

- ◆ 60% of heartburn sufferers consult a physician or pharmacist
- ◆ 79% of consumers with heartburn >1 per week consulted with a physician
- ◆ OTC medication recommended 60% of the time

**Consumers Still See Their Physicians**

IP 10

- ◆ **Fallon Community Healthcare System**
  - 2000 patients with acid-related diseases
  - No change in number of doctor visits
- ◆ **Minneapolis Consumer Survey (1993 and 1997)**
  - Cross-sectional survey 3400 consumers
  - No change mean number of doctor visits
- ◆ **MEDSTAT MarketScan Data Base (1995–1998)**
  - Administrative claims on 7 million people
  - Increased number of doctor visits

## **Unmet Consumer Needs Still Exist**

- ◆ Lack of all day efficacy
  - 63% Antacid users take 2 or more doses/day
  - 42% H<sub>2</sub>RA users take 2 or more doses/day
- ◆ Multiple therapies required to control heartburn
  - 74% daily H<sub>2</sub>RA users also take antacids
- ◆ Consumers want dosing convenience

## **Who Is The Target Population For OTC Omeprazole?**

- ◆ Adult users of OTC heartburn medications
- ◆ Consumers with heartburn who use OTC medications for prevention
- ◆ Consumers with heartburn more than once per week who use OTC medications for relief

**Omeprazole Magnesium — A Solution  
To Important Unmet OTC Consumer Needs**

IP 13

***Unmet Need***

***OTC Ome***

Multiple dosing

24 hour duration

Multiple therapies

Complete prevention

Dosing Convenience

Single tablet

**Considerations for  
Omeprazole OTC Switch**

IP 14

- ◆ Appropriateness of omeprazole for the OTC management of heartburn
- ◆ Effectiveness at doses under consideration
- ◆ Ability of consumer to comprehend instructions and use the product appropriately
- ◆ Safety of use in the OTC setting
- ◆ Benefits of OTC use outweighing potential risk
- ◆ Appropriate labeling for consumer use

## Agenda For Presentation

**Donald Castell, M.D.**  
Professor, Department of Medicine  
The Graduate Hospital, Philadelphia

OTC Population

**Nora Zorich, M.D., Ph.D.**  
Medical Director, Procter & Gamble

Clinical Efficacy

**Bernard P. Schachtel, M.D.**  
Department of Epidemiology & Public Health  
Yale University

Consumer Use Patterns

**Douglas Levine, M.D.**  
Chief Medical Officer, AstraZeneca

Safety

**Nora Zorich, M.D., Ph.D.**

Summary