

PROCTER & GAMBLE COMPANY
ASTRAZENECA LP

Omeprazole Magnesium Tablets

NDA No. 21-229

Advisory Committee
Briefing Document

October 20, 2000

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List of Abbreviations and Definition of Terms

Abbreviation	Definition
AE	Adverse Event
AMI	Astra Merck Inc.
ANOVA	Analysis of Variance
Astra	Astra Hässle
AUC	Area Under the Curve
CI	Confidence Interval
COSTART	Coding Symbols for Thesaurus of Adverse Reaction Terms
ECL	Enterochromaffin-Like
EE	Erosive Esophagitis
FDA	Food and Drug Administration
GEE	Generalized Estimating Equation
GERD	Gastroesophageal Reflux Disease
<i>H. pylori</i>	<i>Helicobacter pylori</i>
H ₂ RA	Histamine H ₂ -Receptor Antagonist
ITT	Intent-to-Treat
LSBE	Long Segment Barrett's Esophagus
MEN	Multiple Endocrine Neoplasia
Merck	Merck and Co., Inc.
mg	Milligram
MUPS	Multiple Unit Pellet System
NDA	New Drug Application
Ome	Omeprazole
Ome-Mg	Omeprazole Magnesium
Ome-Mg 10	Omeprazole Magnesium 10.3 mg
Ome-Mg 20	Omeprazole Magnesium 20.6 mg
OTC	Over-the-Counter
P&G	The Procter & Gamble Company

List of Abbreviations and Definition of Terms (Continued)

Abbreviation	Definition
PK	Pharmacokinetic
PPI	Proton Pump Inhibitors
prn	As Necessary
REALM	Rapid Estimate of Adult Literacy in Medicine
Rx	Prescription
SAE	Serious Adverse Event
SAS [®]	Statistical Analysis System
SD	Standard Deviation
SSBE	Short Segment Barrett's Esophagus
TEN	Toxic Epidermal Necrolysis
t _{1/2}	Elimination Half-Life
U.S. or US	United States
VAS	Visual Analog Scale
vs.	Versus
ZES	Zollinger-Ellison Syndrome

List of Study Numbers and Abbreviations

Abbreviation	Study Number
003	1998003
005	1998005
006	1998006
014	1998014
022	1999022
067	1998067
092	1997092
095	1997095
171	AMI 171
183	AMI 183
200	AMI 200
2782	MRD#US972782
3358	MRD#US973358

Briefing Document Organization

- Part 1 of this document presents the executive summary.
- Part 2 characterizes the heartburn consumer.
- Part 3 presents summaries of the pathophysiology of heartburn and the clinical pharmacology of Ome. This information will be of utility in understanding the results of the clinical trial data from the OTC Ome-Mg program.
- Part 4 provides an overview of the OTC Ome-Mg clinical program.
- Part 5 summarizes the efficacy data from the six pivotal clinical trials: four prevention trials and two relief trials.
- Part 6 summarizes the data from the five consumer use trials.
- Part 7 presents a summary of the various safety data from the OTC and prescription (Rx) clinical trials, as well as a review of the global post-marketing surveillance data.
- Part 8 reviews safety in areas of specific considerations.
- Part 9 reviews the potential for long-term gastric effects.
- Part 10 reviews the masking of serious disease.
- Part 11 reviews rebound of gastric acid secretion.
- Part 12 reviews selected adverse events such as anaphylaxis, angioedema, hepatic function, and visual disturbances.
- Part 13 contains overall safety conclusions.
- Part 14 provides the reference citations.