



AstraZeneca GI Franchise
Dr Martin Nicklasson
Executive Vice President, GI Franchise

GI Franchise highlights

- Nexium® approval in Europe
- Nexium® launch in several countries
- Grants of Nexium® related patents
- Successful defence of intellectual property for Losec®



AstraZeneca objectives in GI

- Continue sales growth of Losec[®]/Prilosec[®]
- Defence of Losec[®]/Prilosec[®] patents
- Successfully launch Nexium[®]
- Extend the opportunities within the GI pipeline

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Losec[®]/Prilosec[®] highlights in 2000

- Losec[®] MUPS[®] approved in 8 and launched in 14 countries
- Expansion of indications in 4 countries
- No additional countries facing generic competition
- 4 Additional ANDAs in the US
- Continued sales growth in the US
- Most prescribed product in the US anti-secretory market
- Losec[®] for long term treatment in Japan

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Pediatric filing status in the US

- 🔗 Filing for pediatric use on schedule
- 🔗 As specified by FDA Modernisation Act, AstraZeneca anticipates receiving an additional 6 months of market exclusivity for Prilosec®

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GI Franchise – intellectual property and litigation

Country	Substance patent expiry	Status
Canada	July 1999	No generics
Denmark	April 1999	No generics
South Africa	April 1999	No generics
Sweden *	April 2000	No generics
Norway *	April 1999	No generics
Hungary	April 1999	No generics

* SPC nullified and under appeal

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GI Franchise – intellectual property and litigation

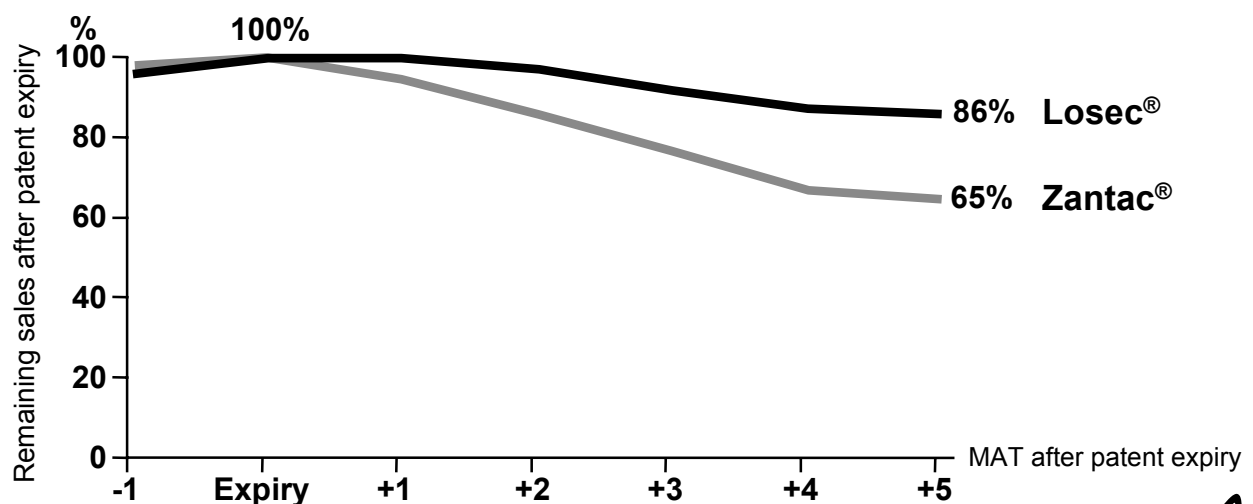
Country	Substance patent expiry	Status
Australia	April 1999	1 generic
Germany *	April 1999	14 generics
Malaysia	April 1999	2 generics
Singapore	April 1999	3 generics
Hong Kong	April 1999	13 generics

* SPC nullified and under appeal

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Sales erosion of Losec[®] vs Zantac[®] at time of patent expiry by quarterly MAT

Countries included: Australia, Canada, Denmark, Germany, Hong Kong, Malaysia, Norway, South Africa



Source: IMS Health




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Status of US litigation processes (omeprazole ANDAs)

Company	Appl. Number	Date of notice	Lawsuits (filing date by AstraZeneca)	Expiry of 30-month stay period
Genpharm	75-268	Apr 1998	May 1998	Oct 2000
Genpharm	75-268	Oct 1998	Nov 1998	Apr 2001
Andrx	75-347	Apr 1998	May 1998	Oct 2000
Andrx	75-347	Jun 1999	Jul 1999	Dec 2001
KUDCo/Schwarz	75-410	Jan 1999	Feb 1999	Jul 2001
KUDCo/Schwarz	75-410	Jul 1999	Aug 1999	Jan 2002
Reddy-Cheminor	75-576	Mar 1999	Apr 1999	Sep 2001
Reddy-Cheminor	75-576	Feb 2000	Mar 2000	Aug 2002
LEK	75-757	May 2000	Jun 2000	Nov 2002
Impax	75-785	Apr 2000	May 2000	Oct 2002
Eon Labs	75-791	Apr 2000	May 2000	Oct 2002
Mylan	75-876	Aug 2000	Sep 2000	Feb 2003

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Status of US litigation process (omeprazole ANDAs)

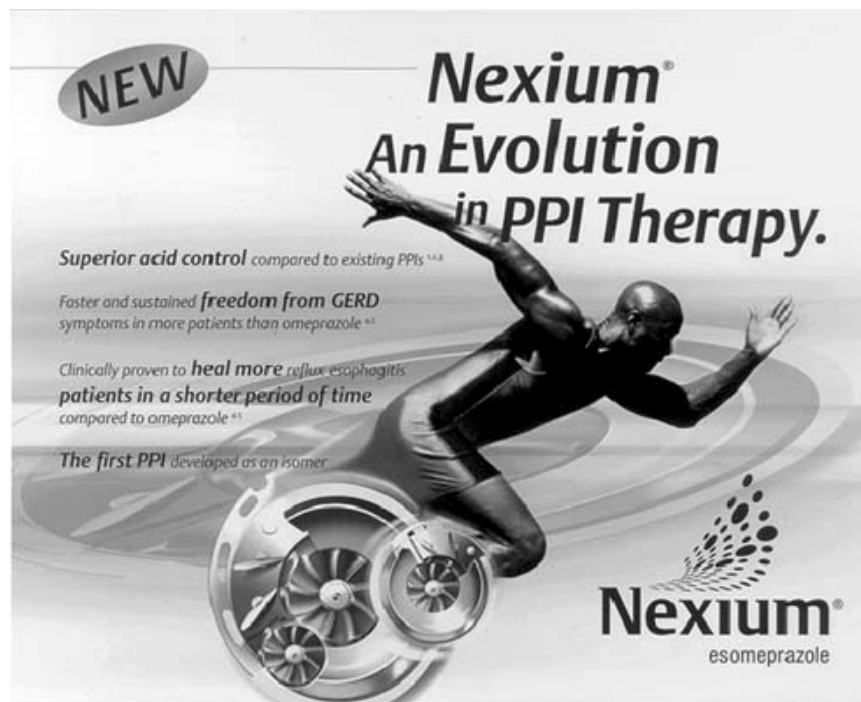
-  Pre-trial schedule extended by 2 months, until December 2000
-  Expert depositions completed
-  Summary judgement motions filed

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In summary – Losec®/Prilosec®

- ✦ The MUPS® tablet launched in 14 countries in 2000
- ✦ Filing for pediatric use on schedule in US
- ✦ Sales - post-substance patent expiry - significantly better maintained compared to other models
- ✦ Compared to 1999, no additional countries facing generic competition
- ✦ The US pre-trial schedule extended by 2 months

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NEW

Nexium®

An Evolution in PPI Therapy.

Superior acid control compared to existing PPIs ^{1,2,3}

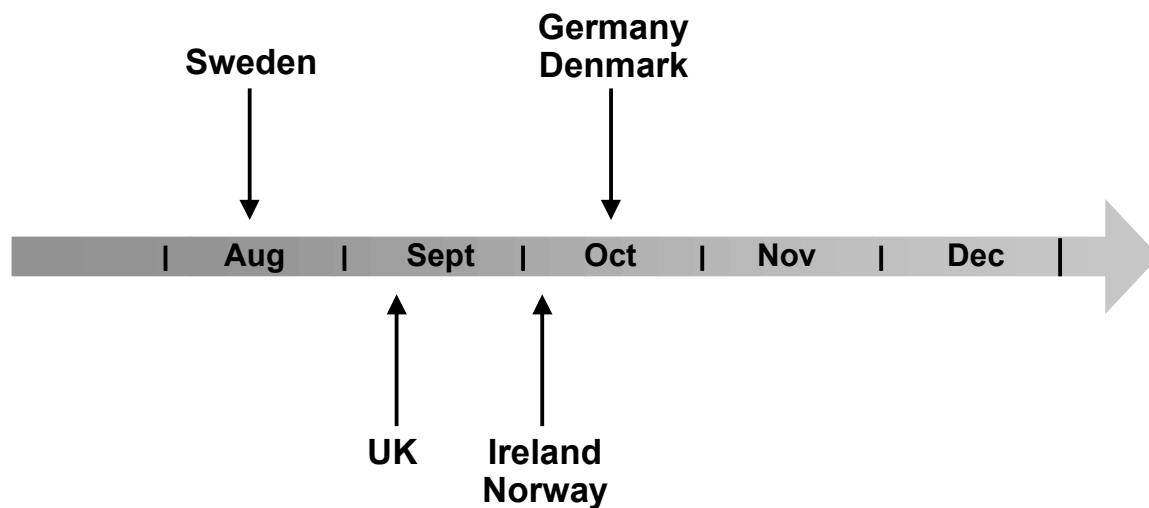
Faster and sustained freedom from GERD symptoms in more patients than omeprazole ^{4,5}

Clinically proven to heal more reflux esophagitis patients in a shorter period of time compared to omeprazole ^{6,7}

The first PPI developed as an isomer

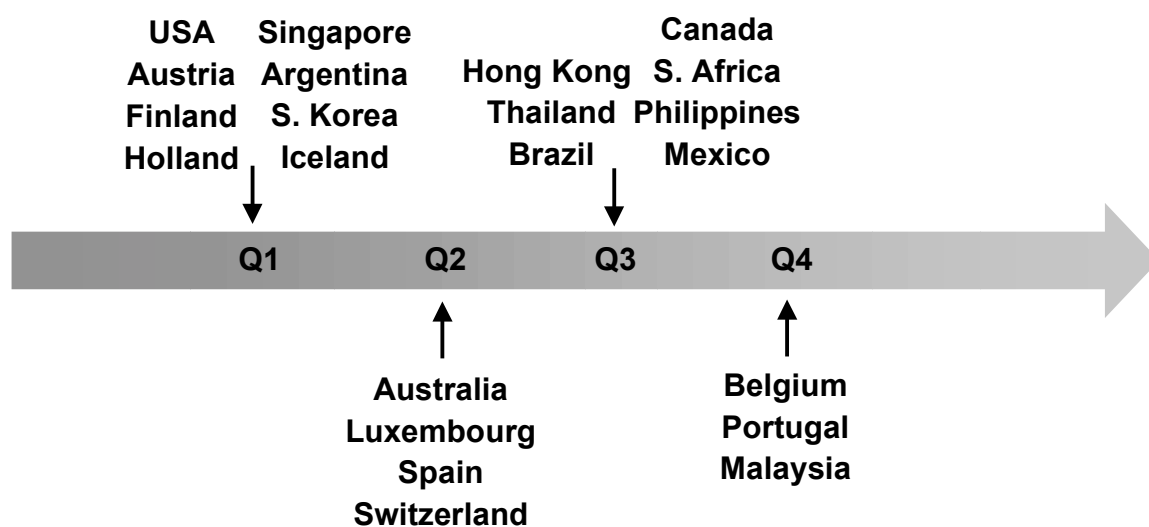
Nexium®
esomeprazole

Nexium® – launches in 2000



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Nexium® – launches in 2001



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US launch of Nexium®

Strategic Platform

- Drive demand through megabrand levels of promotion:
 - Professional initiatives
 - Consumer initiatives
- Provides value to managed care and consumers

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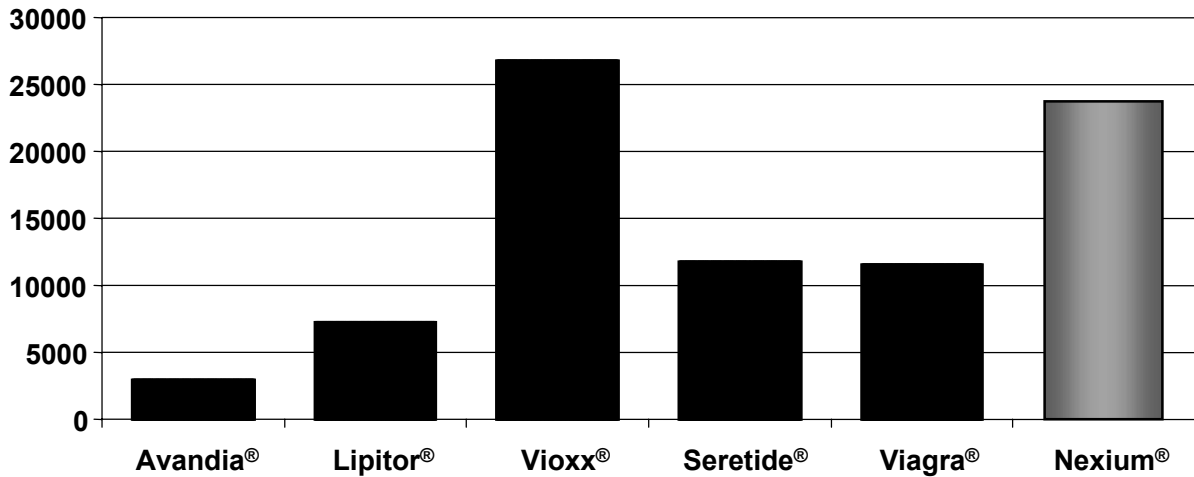
Initial reactions to Nexium® in its first markets

- High awareness in the market place
- Highly positive reactions from doctors:
 - Improved acid control and clinical efficacy
 - ‘On demand’ concept attractive
 - Value for money
- Rapid uptake

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UK launch of Nexium®

Cumulative Rx's

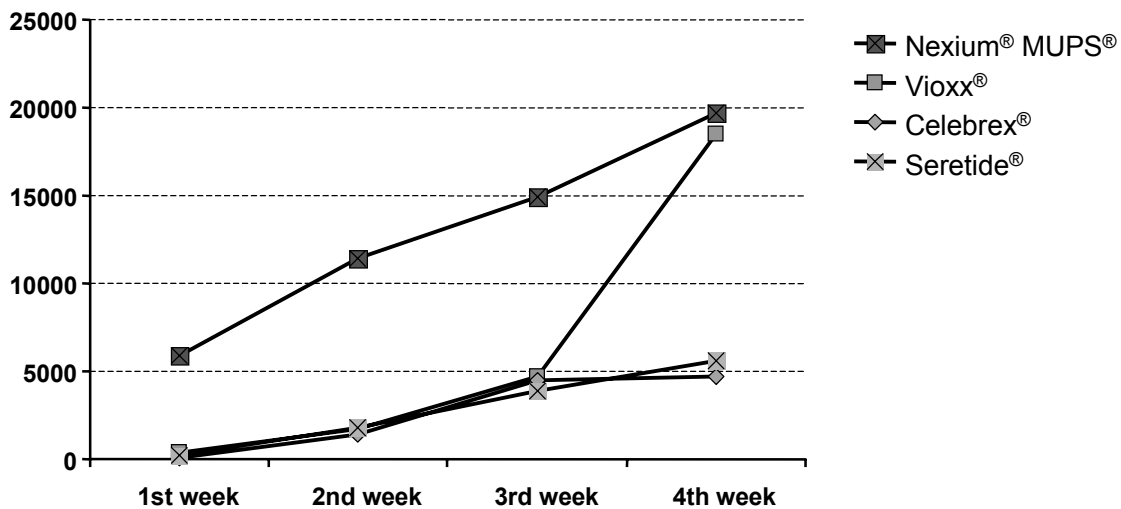


Source: Scriptcount (10 week data)

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German launch of Nexium®

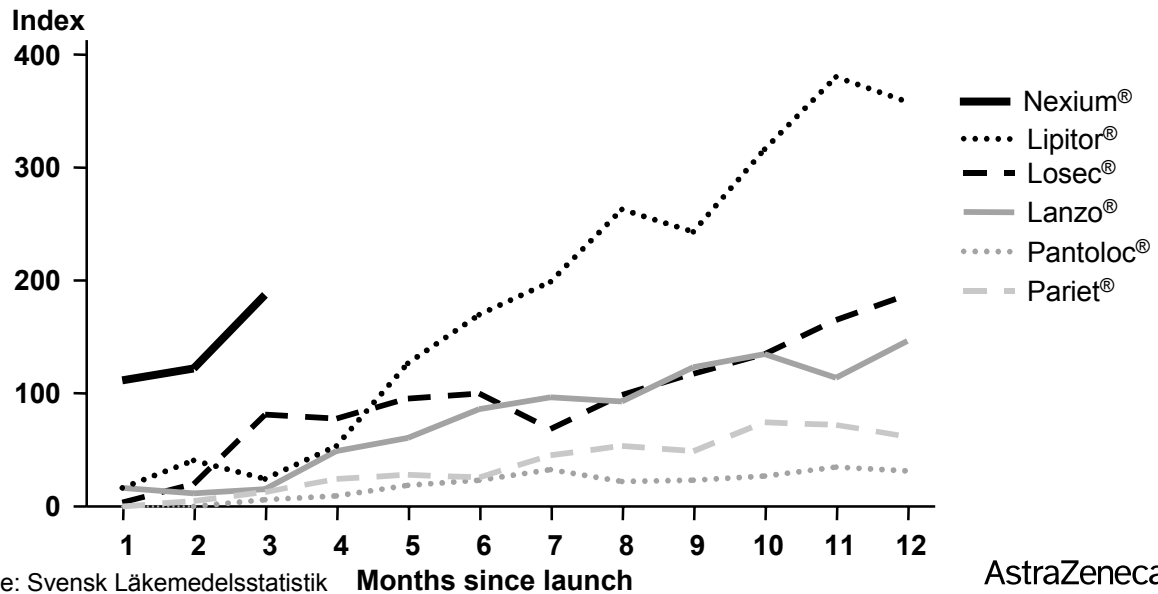
Weekly Rx's



Source: Pharmatrend (4 week data)

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Swedish launch of Nexium®



NEW

Nexium® An Evolution in PPI Therapy.

Superior acid control compared to existing PPIs ^{1,2,3}

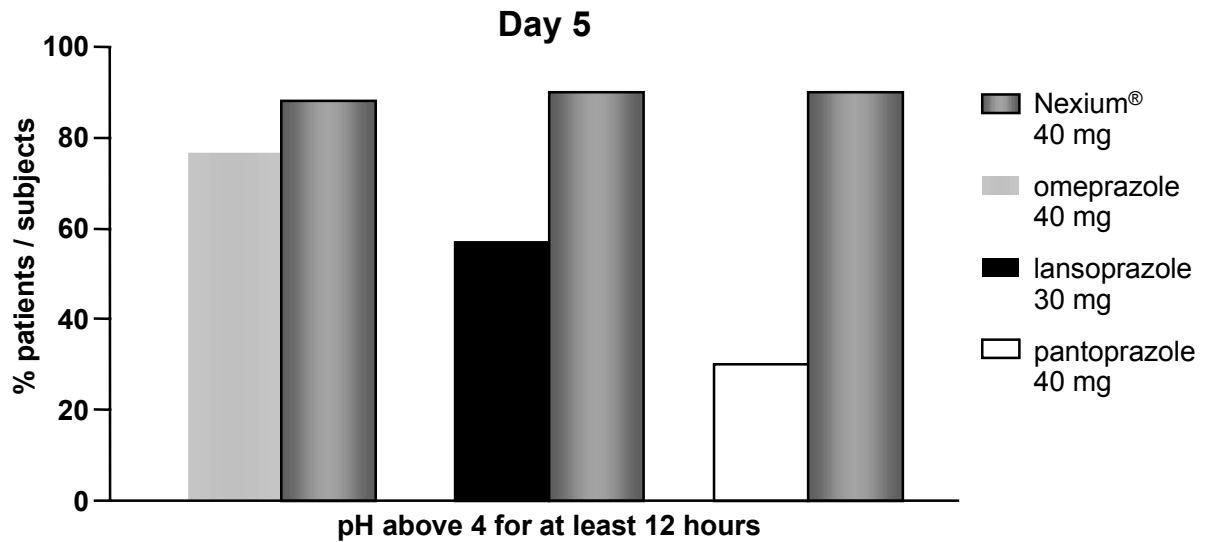
Faster and sustained freedom from GERD symptoms in more patients than omeprazole ^{4,5}

Clinically proven to heal more reflux esophagitis patients in a shorter period of time compared to omeprazole ^{6,7}

The first PPI developed as an isomer.

Nexium®
esomeprazole

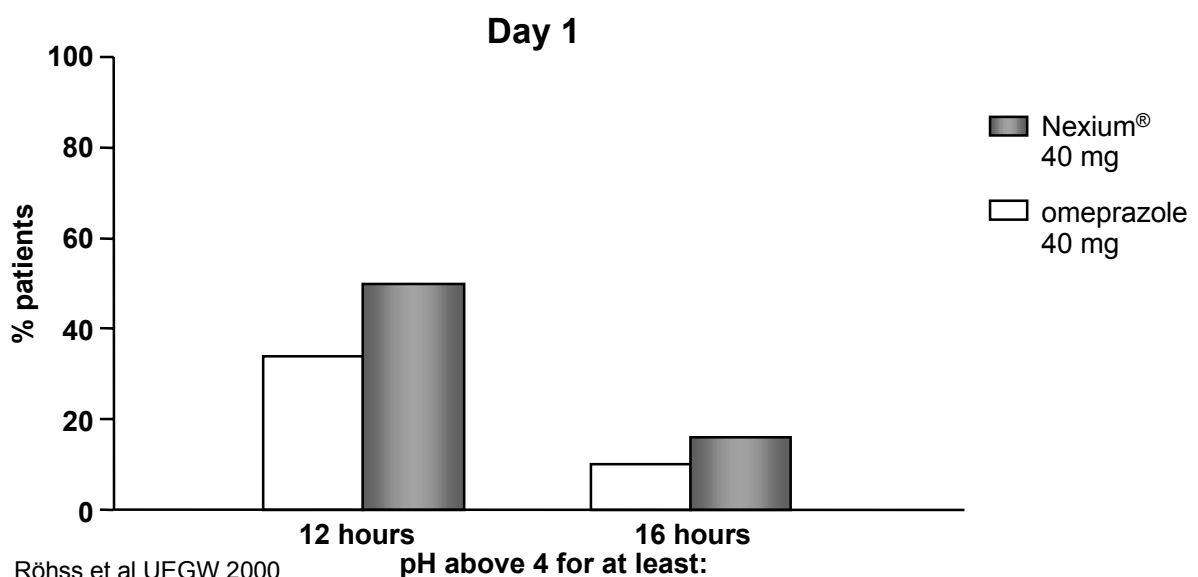
Acid control



Röhss et al Nordic Gastro 2000, Thomson et al DDW 2000, Wilder-Smith et al DDW 2000
 P < 0.05 percentage of time with intragastric pH above 4 during 24 hours



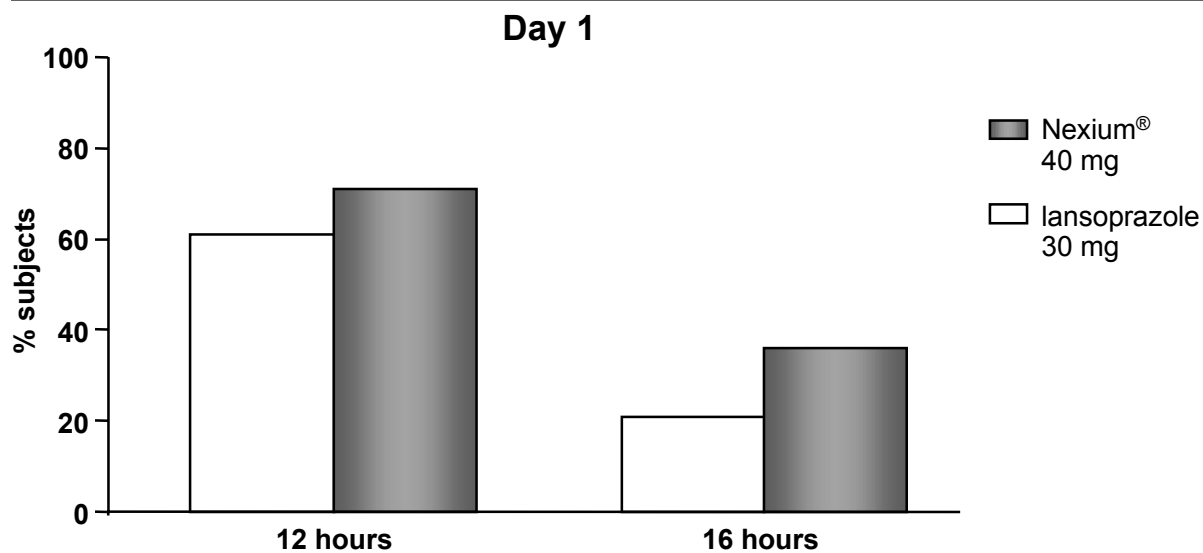
Acid control



Röhss et al UEGW 2000
 P < 0.001 percentage of time with intragastric pH above 4 during 24 hours



Acid control

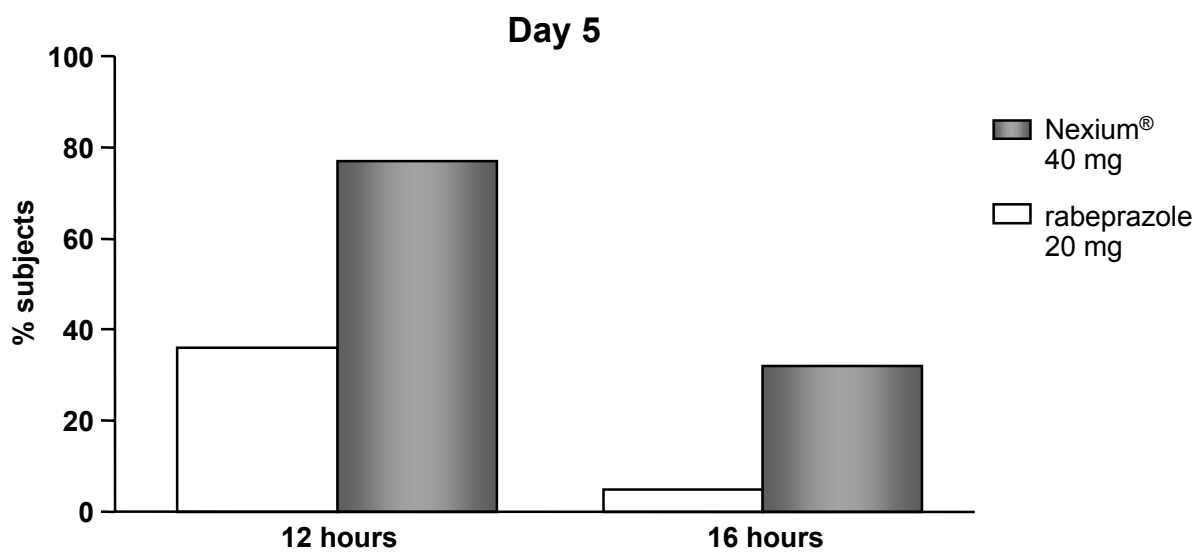


Thomson et al UEGW 2000

pH above 4 for at least:
P < 0.005 percentage of time with intragastric pH above 4 during 24 hours

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Acid control

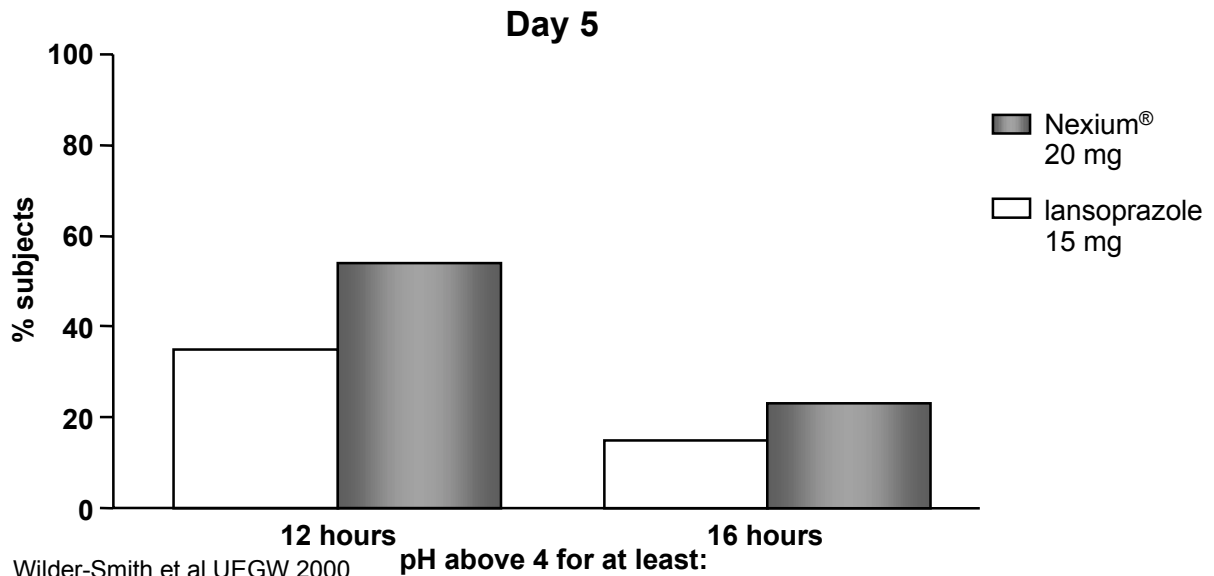


Wilder-Smith et al UEGW 2000

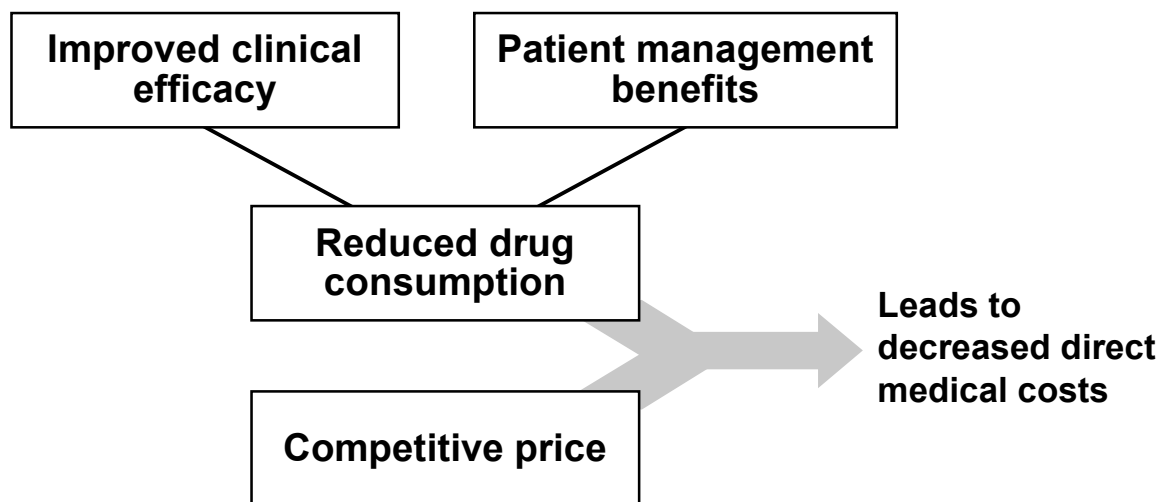
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Acid control

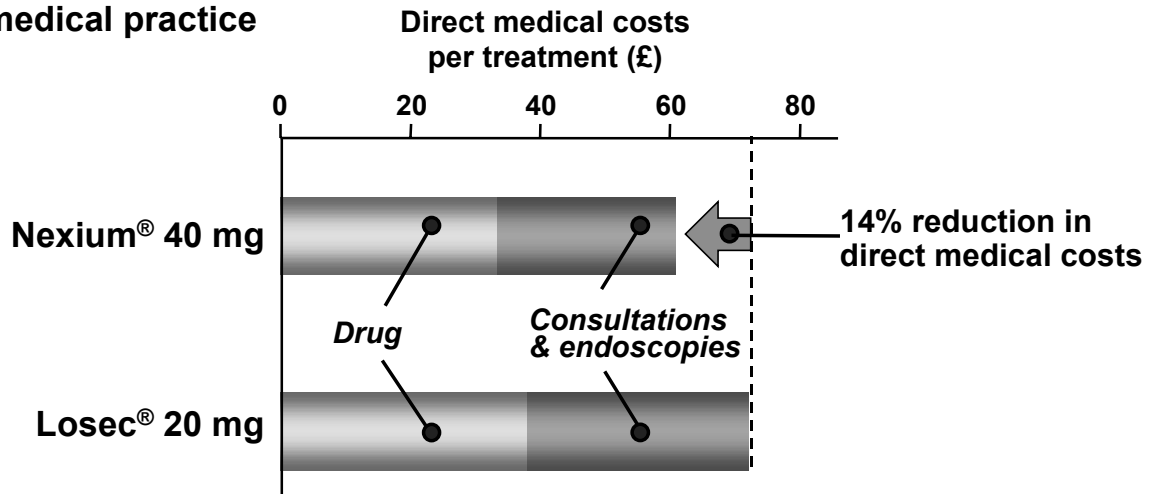


Nexium[®] leads to economic benefits



Clinical superiority of Nexium® in healing erosive esophagitis leads to reduction in costs

UK medical practice



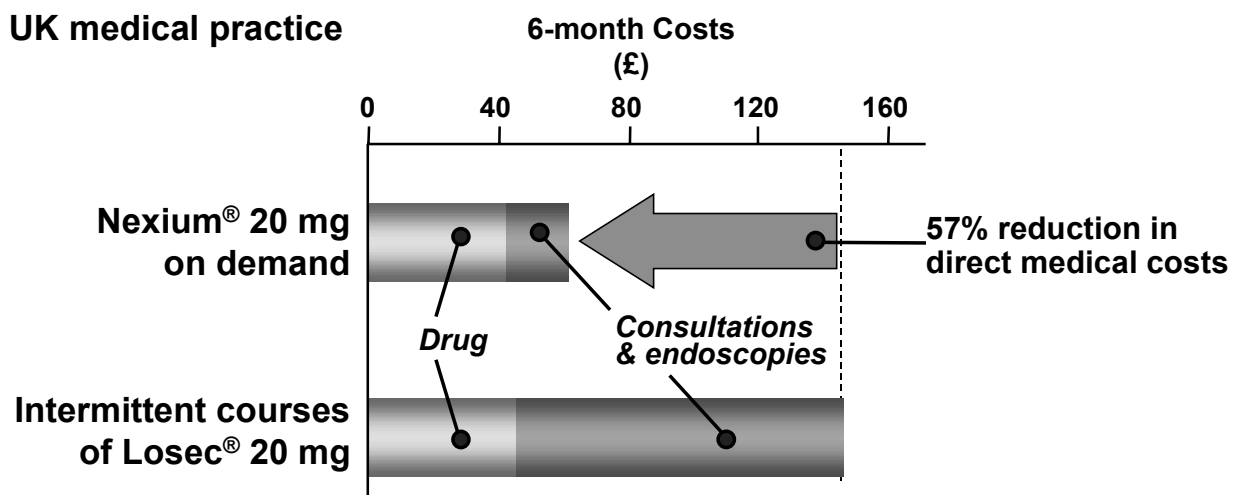
Wahlqvist P 2000, ISPOR (abstract)

Kahrilas PJ 2000, Aliment Pharmacol Ther. Richter JE, 2000 Gastroenterol

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Nexium® 20mg on-demand reduces direct medical costs in GERD compared with intermittent treatment

UK medical practice



Wahlqvist P 2000, ISPOR (abstract)

Talley 2000, Gastroenterology. Talley 2000, Gastroenterology

Carlsson 1997, Euro J Gastroenterol Hepatol

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Ongoing key studies

- More than 30,000 patients in clinical trials globally
- Comparative studies against other PPIs
- Treatment of GERD patients with 5 year follow-up
- Health economics in GERD

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Ongoing sNDAs

- Dyspepsia
- Treatment of NSAID GI side-effects
- Treatment of children with GERD
- Parenteral formulation

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In summary – Nexium®

- Successfully launched in 6 European markets with high awareness and positive reactions from doctors
- New data confirm improved acid control versus all other PPIs
- Provides value for money compared to standard treatment with Losec®
- Comparative studies with other PPIs ongoing
- Several sNDAs in development

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In conclusion

- AstraZeneca is well prepared to win the game
- Our GI strategy is built on:

Aggressive defence

- Losec®/Prilosec® intellectual property

Strong offence

- Nexium® and reversible acid pump inhibitor

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