

*Out* performance ..



Capsules  
**Eso-protocol**   
Esomeprazole 40mg

# Eso-protocol<sup>e</sup>

Capsules  
Esomeprazole 40mg

## Outperformance Medicine ...

- Superior acid control compared with other PPIs
- Effective resolution of GERD symptoms
- Superior healing power
- Assured maintenance of healing
- Significant improvement in quality of life
- Cost effective

### Therapeutic Indications & Recommended Dosage Schedule

#### **Gastroesophageal Reflux Disease (GERD)**

- Healing of erosive Oesophagitis (EE)  
20mg or 40mg Once daily for 4 to 8 weeks

#### **Maintenance of Healing of EE**

- 20 mg Once daily

#### **Symptomatic GERD**

- 20 mg Once daily for 4 weeks

#### **Risk Reduction of NSAID Associated Gastric Ulcer**

- 20mg or 40 mg Once daily for up to 6 months

#### **Helicobacter pylori Eradication**

#### **Triple therapy**

- Esomeprazole 40 mg Once daily for 10 days
- Amoxicillin 1000 mg Twice daily for 10 days
- Clarithromycin 500 mg Twice daily for 10 days

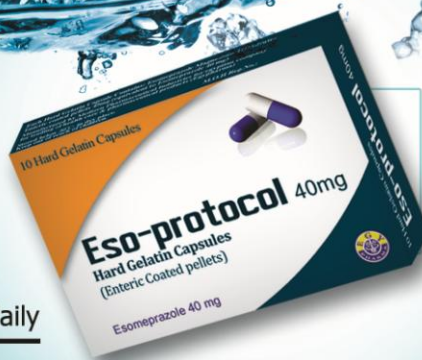
#### **Pathological Hypersecretory Conditions**

- Zollinger-Ellison Syndrome 40mg Twice daily

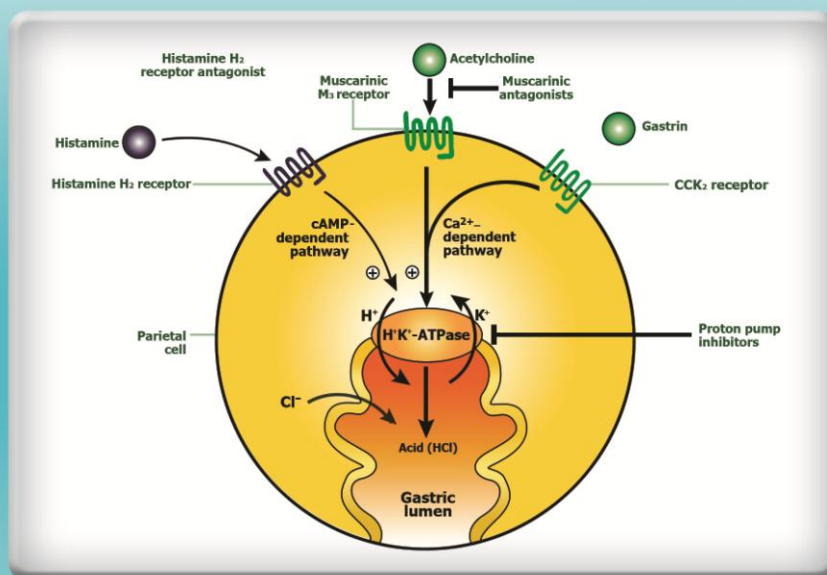
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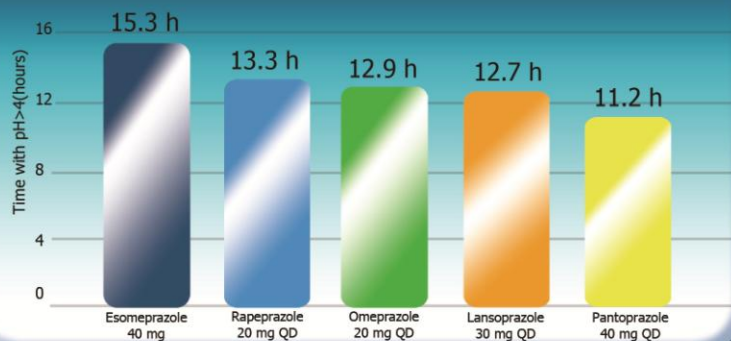


## Distinctive Mechanism of Action



## Provides Superior Acid Control <sup>(1-8)</sup>

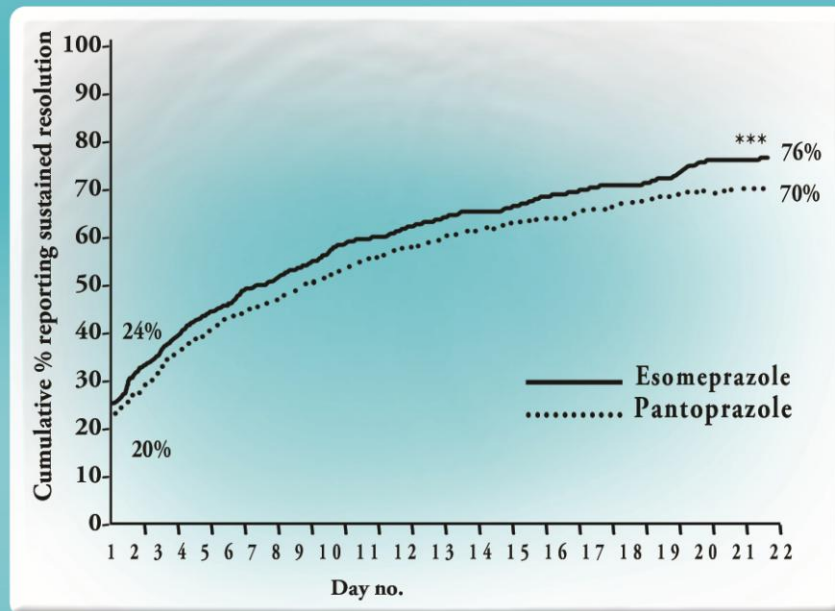
In 2 intragastric pH studies  
Greatest number of hours with intragastric pH>4 over a 24-hour period



Day 5 data from a randomized, open-label, comparative, 5-treatment, 5-way crossover study comparing mean pharmacodynamic parameters in patients with symptoms of GERD, treated once daily for 5 days with at least a 10 days washout period.

### Overall Effective Control<sup>(16)</sup>

Cumulative proportion of patients reporting sustained resolution of heartburn (the first of seven consecutive days without heartburn as judged from daily diary cards during treatment with Esomeprazole 40mg or Pantoprazole 40mg (intent- to- treat population)  $p < 0.001$  vs. Pantoprazole 40mg.

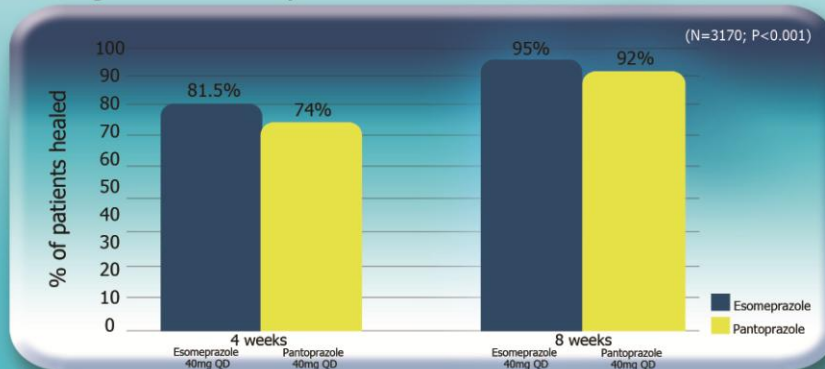


A randomized comparative study of Esomeprazole 40mg. versus Pantoprazole 40 mg for healing erosive oesophagitis; (the EXPO study)

“GERD is a chronic disease that frequently affects health-related quality of life, and if not probably managed the complications of GERD may include erosive oesophagitis”

## Healing Scenario is Going On

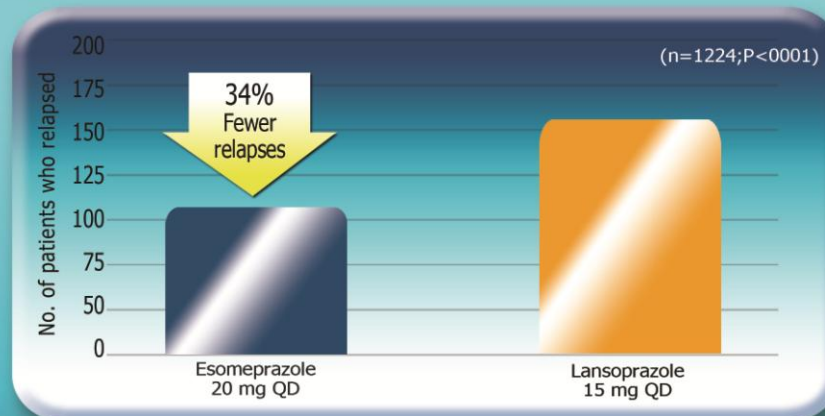
### ► Healing Vs. Pantoprazole<sup>(16)</sup>



A randomized comparative study of Esomeprazole 40mg versus Pantoprazole 40mg. for healing erosive Oesophagitis; ( EXPO study).

## Assured Maintenance Of Healing Of EE<sup>(17-19)</sup>

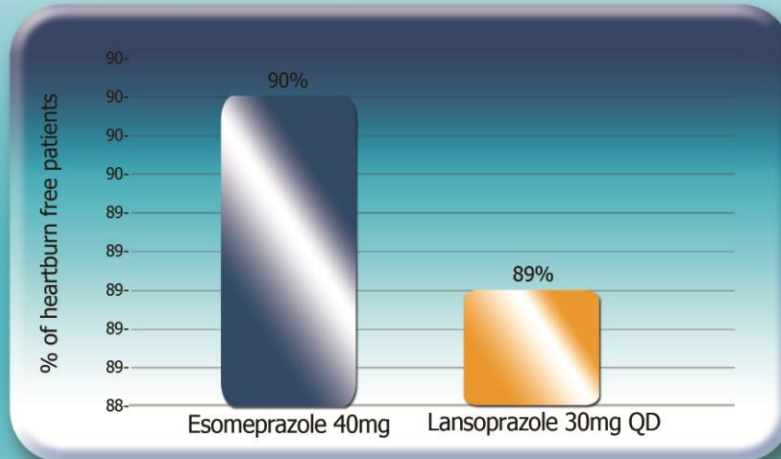
### ► Fewer relapses of EE through 6 months in GERD patients across varying grades of EE



- In a second 6-month study, 37% fewer relapses across varying graded of EE. were seen with Esomeprazole 20 mg QD vs. Lansoprazole 15mg QD (n=1001;P=.0007)
- Esomeprazole 20mg and Lansoprazole 15mg are the FDA-approved doses for the maintenance of healing of EE.
- Relapse defined as endoscopic erosions and/or recurrent symptoms leading to patient-initiated withdrawal from the study
- Data from a multicenter . randomized, double-blind, parallel-group, 6-month trial comparing oral doses of Esomeprazole 20mg with Lansoprazole 15mg. administered once daily in patients with endoscopically confirmed healed EE. with Esomeprazole 40mg.

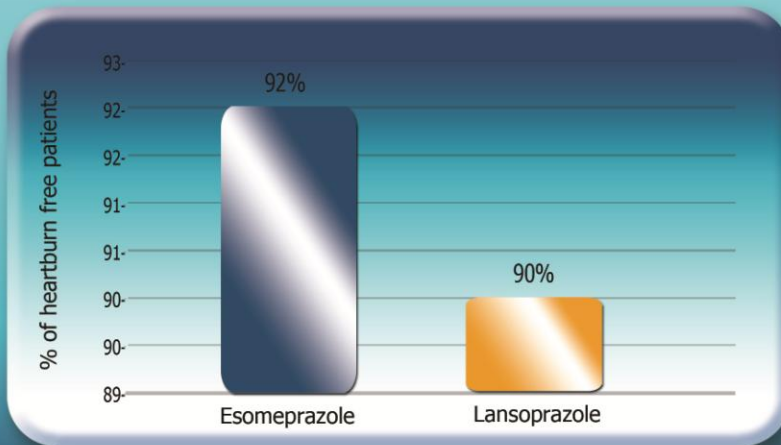
## An Effective Evolution in GERD Symptoms Management <sup>(16)</sup>

### ▶ Daytime Heartburn Relief



90% of patients taking Esomeprazole 40 mg QD (n=2521) reported daily heartburn relief at week 4, and 89% of patients experienced daily heartburn relief with Lansoprazole 30 mg QD (n=2516; P=NS)

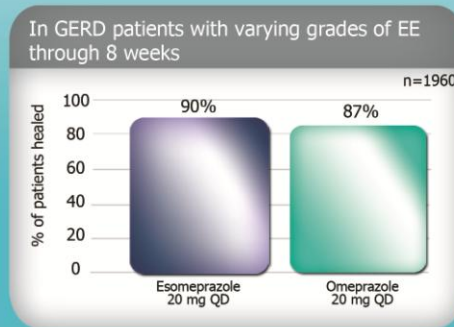
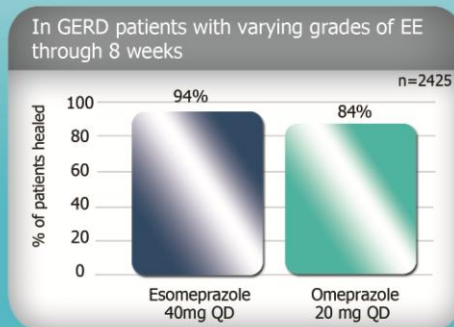
### ▶ Night-time Heartburn Relief <sup>(16)</sup>



92% of patients taking Esomeprazole 40mg. QD (n=909) reported heartburn-free nights at week 4, and 90% of patients experienced heartburn-free nights with Lansoprazole 30mg. QD (n=951; P=NS).

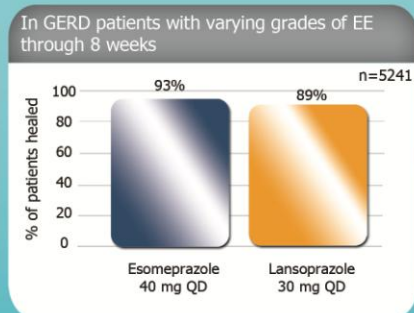
Provides Excellent Healing of EE

▶ Healing Vs. Omeprazole <sup>(9-15)</sup>

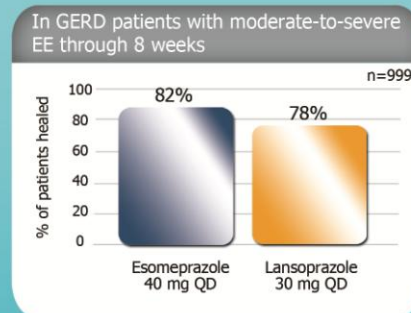


Data from multicenter, randomized, double-blind trials comparing oral doses of Esomeprazole vs. Omeprazole, administered once daily to patients with endoscopically diagnosed EE.

▶ Healing Vs. Lansoprazole <sup>(9-15)</sup>

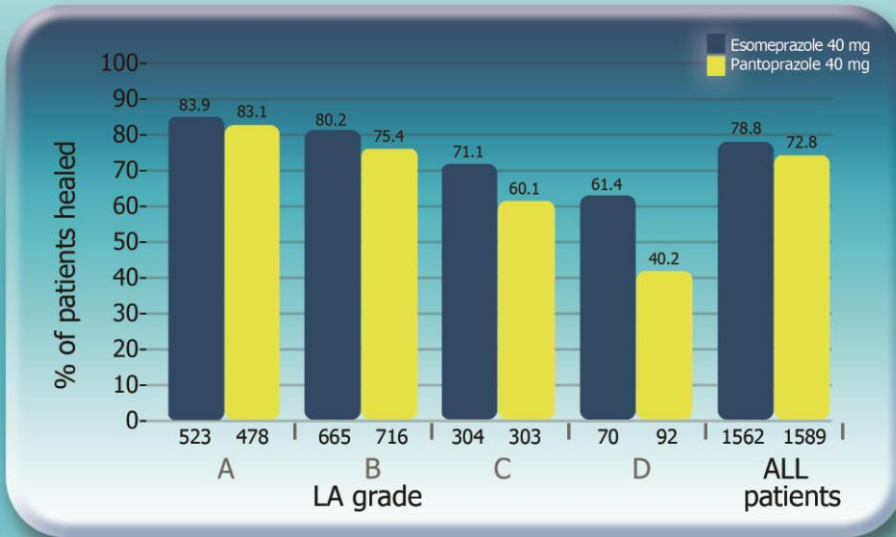


Primary endpoint from a multicenter, randomized, double blind, parallel-group, 8-week trial comparing oral doses of Esomeprazole 40 mg with Lansoprazole 30mg. administered once daily to patients with endoscopically diagnosed EE.



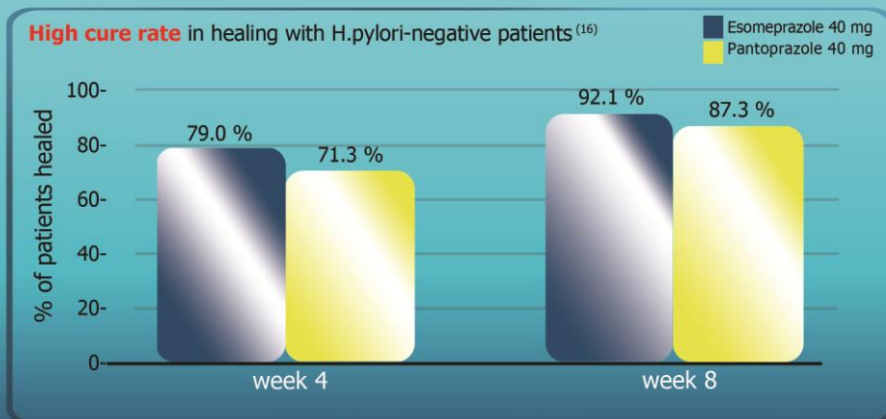
Moderate-to-severe EE. defined as LA grades C and D erosive oesophagitis. Primary endpoint from a multicenter, randomized, double blind, parallel-group, 8-week trial comparing oral doses of Esomeprazole 40mg. with Lansoprazole 30mg. administered once daily to patients with endoscopically diagnosed EE. Esomeprazole 40 mg, Esomeprazole 20 mg, Omeprazole 20 mg, and Lansoprazole 30mg. are the FDA-approved doses for the healing of EE.

**Management of Complications Is Essential** <sup>(16)</sup>



Erosive Esophagitis observed healing rates after 4 weeks treatment with either Esomeprazole 40 mg or Pantoprazole 40 mg by baseline severity (intent-to-treat population). chi-squared test: \*P<0.05. \*\*P< 0.01 vs. pantoprazole. Mantel-haenzel test stratified by baseline severity :\*\*\*P< 0.001 vs. pantoprazole.

**Up to Challenge in Hard Missions**



Erosive Oesophagitis observed healing rates among helicobacter pylori-negative patients at 4 and 8 weeks of treatment with Esomeprazole 40 mg (n=1078) or Pantoprazole 40mg (n=1113) intent-to-treat population \*\*\*P<0.001. \*\*\*\*P<0.0001 vs. Pantoprazole.