

Esomeprazole 20 & 40 mg

Enteric coated pellets in capsules



Superior acid control compared to other Proton Pump Inhibitors

Key features

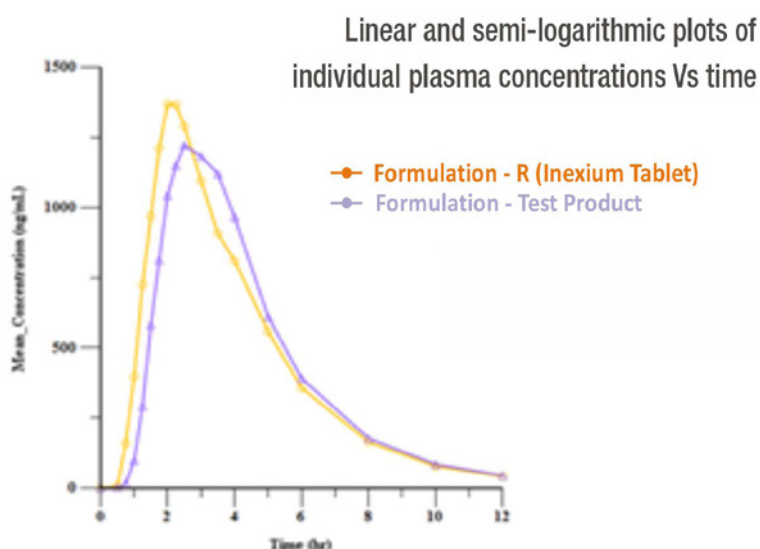
- Enteric coated pellets formulation ensures a stable and improved pharmaceutical composition guaranteeing esomeprazole integrity until it reaches the proximal part of the small intestine, hence facilitating its absorption.

Competitive advantages

- First single stereospecific S-isomer of omeprazole less prone to first-pass metabolism¹.
- Higher bioavailability than omeprazole².
- Superior acid control compared with all other Proton Pump Inhibitors (omeprazole, pantoprazole, lansoprazole & rabeprazole)^{3, 4, 5, 6, 7}.

Regulatory status

- INN: Esomeprazole
- ATC Code: A02BC05
- CAS Registry Number: 161796-78-7
- Reference compound: INEXIUM[®], AstraZeneca.
- BioEq. study
 - Patient population: 54 fasting adult healthy volunteers.
 - Methodology: Randomized, single-dose, Tw treatments, two sequences, two period crossover.
 - Reference product: INEXIUM[®] 20 & 40 mg, AstraZeneca, France.
- Zone II & IV stability data available.
- eCTD dossier available.



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GASTROENTEROLOGY

Information at a glance

- Commercial batch size / strength (million doses): 20 mg: 3 | 40 mg: 1.5
- Dossier Batch size / strength (million doses): 20 mg: 1 | 40 mg: 0.5
- Shelf-life: 2 years
- Storage & Transport conditions: Room temperature between 20 & 25°C
- Pack info / strength: Alu-Alu. 7-caps blister pack
- Tablet weight / strength: 20 mg: 87.51 mg | 40 mg: 175.02 mg
- Capsule size: 20 mg: 4 | 40 mg: 3

Market highlights

- The Gastroesophageal Reflux Disease (GERD) therapeutic market is expected to reach \$4,34 billion by 2025⁸.
- Every year in the US more than 80 million of patients suffer from GERD, of which 75% on a monthly basis.
- Global Peptic Ulcer therapeutic market size was \$4.3 billion in 2019 and is projected to reach \$5.1 billion by 2027 growing at a CAGR of 2.4% from 2020-2027⁹.

Competitors' landscape

- Antacids (GAVISCON[®], MAALOX[®], PHOSPHALUGEL[®]), H2 receptor blockers (TAGAMET[®]/cimetidine, AZANTAC[®]/ranitidine), Proton Pump Inhibitors (PRILOSEC[®]/omeprazole, INIPOMP[®]/pantoprazole, LANZOR[®]/lansoprazole, PARIET[®]/rabeprazole).

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8. *Gastroesophageal Reflux Disease Therapeutics Market Size Report by Grand View research (2016)*
9. *Peptic Ulcer Drug Market report by Fortune Business Insights (2020)*



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Key numbers

- More than 80 million of patients suffer from GERD in the USA
- Global Peptic ulcer market expected to reach \$5.13 billion by 2027
- CAGR 2020-27: 2.4%

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