



1. Introduction

OD-PEP™ is a novel drug delivery based fixed dose combination therapy for Gastroesophageal Reflux Disease (GERD) and Non-ulcer Dyspepsia (NUD). It is a combination of a Proton Pump Inhibitor (PPI) and a prokinetic agent.

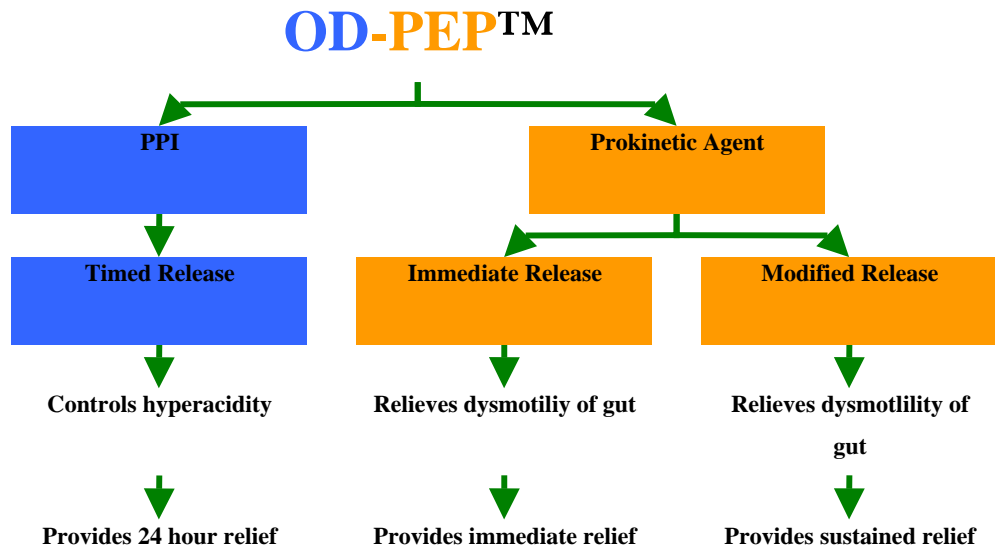
Usually PPIs are administered once a day, while prokinetic agents are prescribed thrice daily. In **OD-PEP™**, an advance drug delivery system has been utilized to tackle the problem of different dosing frequencies of these two drugs. It not only ensures higher patient compliance through a convenient one a day dosage but also reduces acid secretion and increases gut motility

2. Medical need

Proton pump inhibitors are a group of drugs whose main action is pronounced and long-lasting reduction of gastric acid production. Prokinetic agents increase the tone of the lower esophageal sphincter and enhance gastric emptying. It facilitates gastrointestinal smooth muscle activity by inhibiting dopamine at the D1 receptors. A combination therapy of a prokinetic agent and a gastric acid lowering compound is rational and is more effective than mono therapy. A PPI and a prokinetic agent act as an alternative to each of them separately in case of failure.

However, considering the large number of pills that must be taken in such a therapy, the compliance to such a treatment maybe a problem. **OD-PEP™** conveniently fills this gap due to its single dose once a day regime.

3. OD-PEP™ Drug delivery system



4. Clinical experience

An open labelled, multi-centric, non comparative, non randomized trial to evaluate the efficacy & safety of fixed dose combination of Pantoprazole and Domperidone (**OD-PEP™**) in 124 patients with GERD & NUD

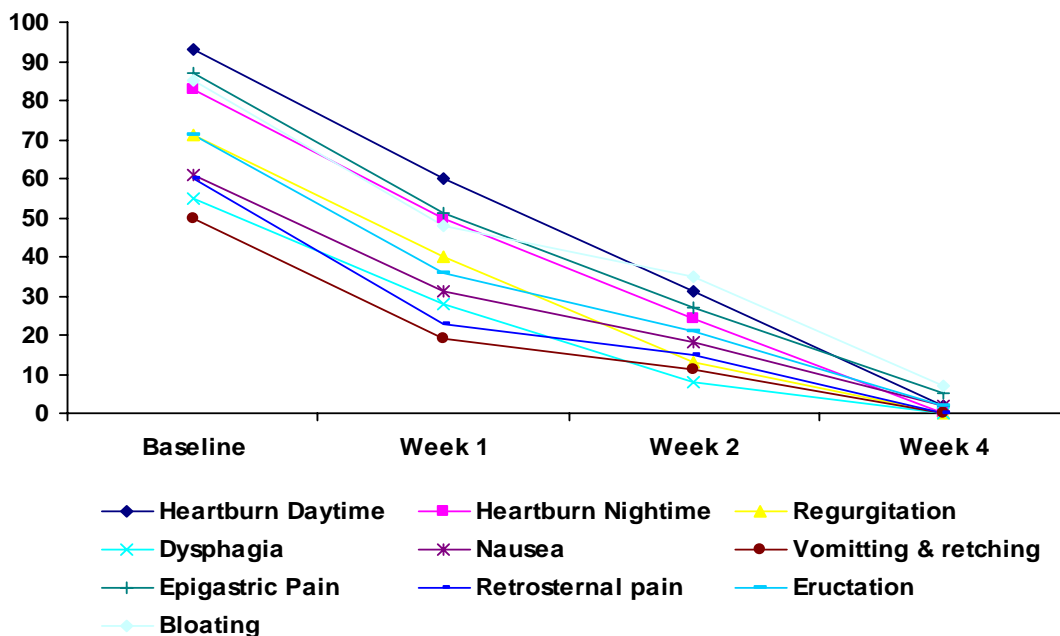


Fig 1 : Frequency of patients with different symptoms of GERD/NUD at baseline to week 4

Safety

Out of 124 patients, two patients reported diarrhea at week 1, 1 patient each complained of dyspepsia at week 1 and week 2 respectively and 1 patient each reported metallic taste at week 1 and week 2. However all these adverse events were mild in nature and did not warrant any discontinuation of therapy.

Conclusion

The study demonstrates that the fixed dose combination of Pantoprazole and Domperidone offers high efficacy in improving the symptoms of GERD / NUD, favorable adverse events profile and complimentary pharmacodynamics.

5. Patent Status

Products patents have been filed in all major countries across the globe and already granted in some of the countries

6. Development Status

- ▪ Commercialized in the Indian market
- ▪ CTD compilation under process for regulated markets

7. Product presentation

ODIPEP™ *

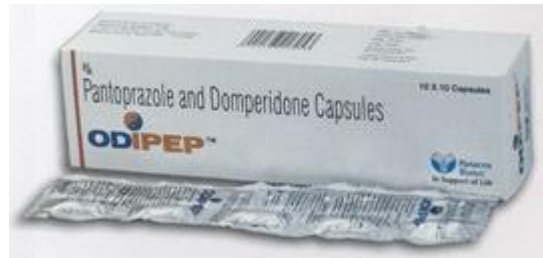
Pantoprazole & Domperidone
Capsules

Each EHG capsule contains

Domperidone BP 10mg
(one white film coated tablet)

Domperidone BP 10mg
(one delayed release tablet)

Pantoprazaole Sodium
Sesquihydrate 40mg
(one enteric coated yellow
tablet)



*** The brand name has now been changed to OD-PEP™**