UKMi MIDLANDS

TRENT MEDICINES INFORMATION SERVICE

QIPP Detail Aid

Providing support for quality in prescribing

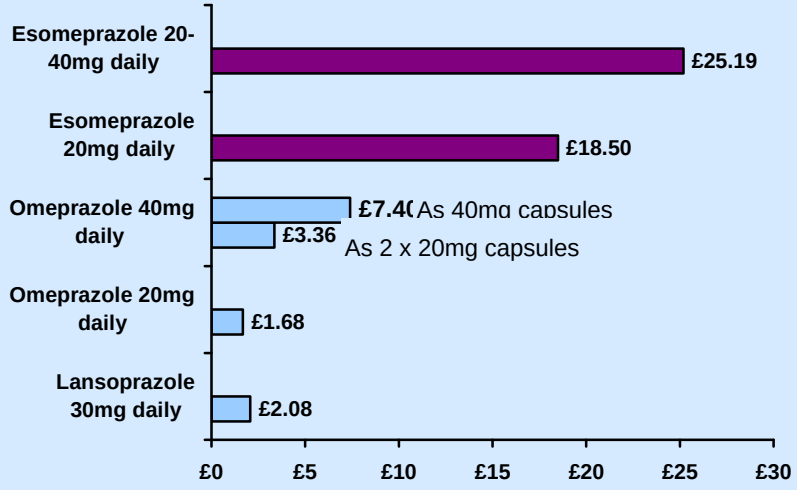
NHS

ESOMEPRAZOLE-WORTH THE EXTRA?

WHAT IS THE PROBLEM?

- In the financial year 2009/ 2010 the East Midlands spent nearly £4million on esomeprazole. If this was all prescribed as omeprazole, there would be saving of nearly £3million. Even if only the 20mg strength was switched to omeprazole, this would free up over £1.5million in the East Midlands.
- Differences between the proton pump inhibitors (PPIs) in terms of clinical efficacy and safety are minimal in most situations.
- The licence for esomeprazole is much more restricted than some other PPIs. It is not licensed for maintenance or treatment of benign gastric or duodenal ulcers or for dyspepsia.
- **ADD LOCAL DATA HERE**

WHAT ARE THE COSTS?



Costs for 28 days supply. Taken from Drug Tariff February 2011
Doses are a guide and do not imply therapeutic equivalence.

WHAT IS THE EVIDENCE?

- There is no evidence that any PPI is more effective than another when compared at equivalent doses for dyspepsia or GORD in the absence of erosive disease. NICE recommendations for the use of PPIs in the management of dyspepsia are that the least expensive PPI is used.
- Esomeprazole is an enantiomer of omeprazole. The licensed dose of omeprazole and esomeprazole for GORD is 20mg once daily and this is considered a full dose of both drugs. If endoscopically confirmed severe or erosive oesophagitis is present, then the dose of either drug should be doubled to 40mg daily for up to 4 weeks.
- The majority of comparative trials between esomeprazole and another PPI have compared non-equivalent doses (eg esomeprazole 40mg vs omeprazole 20mg). In the very few trials which have compared PPIs at doses considered to be equivalent, most have shown no statistically significant differences between the drugs used.

KEY MESSAGES

- **Use omeprazole or lansoprazole (depending on local formularies) as first-line PPI.**
- **There is no evidence that esomeprazole is clinically superior to other PPIs at equivalent full doses for GORD or non-erosive oesophagitis.**
- **Esomeprazole is not licensed for dyspepsia or for maintenance or treatment of benign gastric or duodenal ulcers and should not be used for these conditions.**
- **Patients taking esomeprazole should be reviewed. Consider a switch to an equivalent dose of omeprazole or lansoprazole (depending on local formularies) for all non-specialist conditions.**

Date of Preparation: February 2011

UKMi
UK Medicines Information
MIDLANDS

NHS

Further Information

Development of esomeprazole

Esomeprazole is the S-isomer of omeprazole. It is reported to have greater activity than the racaemic mixture (omeprazole) due to the significantly lower activity of the R-isomer. Therefore the same degree of acid suppression can be produced with lower doses of esomeprazole compared with omeprazole.

There is little evidence to suggest that this additional potency translates into clinically significant benefit for the majority of patients compared with other PPIs at equivalent doses.

Both S- and R-omeprazole are pro-drugs, which are converted in the parietal cell to the active proton pump inhibitor. Unlike the pro-drug, the active drug does not have a distinct chiral isomer, so the structural difference between the pro-drugs has no bearing. Therefore, increasing the dose of omeprazole has an identical clinical effect to using esomeprazole and without evidence of any difference in adverse effects.

The majority of comparative trials have used a dose of esomeprazole at 40mg daily and compared it to omeprazole 20mg or lansoprazole 30mg daily. Only three published trials have compared equivalent licensed doses of the products in reflux oesophagitis (2 trials) or non-erosive disease (1 trial). Two trials showed no statistically significant differences between the drugs given at 20mg daily. In only one trial was there a statistically significant difference between esomeprazole and omeprazole at 20mg daily: the percentage of patients with endoscopically confirmed healing and relief from symptoms was 86.9% with omeprazole and 89.9% with esomeprazole. The clinical significance of this difference is likely to be limited.

Key points for management of dyspepsia

- The NICE clinical guideline *Dyspepsia: Managing dyspepsia in adults in primary care* (CG17) recommends the use of a PPI for 1 or 2 months as an initial strategy for gastro-oesophageal reflux disease (GORD). It also recommends the use of a PPI for 1 month for uninvestigated dyspepsia if medication review and lifestyle advice prove ineffective.
- NICE recommends a 'test and treat' strategy for *H. pylori* for patients who have: a) peptic ulcer disease, b) endoscopically determined non-ulcer dyspepsia, and c) uninvestigated dyspepsia as an alternative to empirical treatment with PPIs
- Patients requiring long-term management of dyspepsia symptoms should be offered an annual review of their condition and be encouraged to try stepping down to 10mg omeprazole/ 15mg lansoprazole, stopping PPI treatment or move to on-demand therapy.
- It is important that the efficacy and availability of PPIs does not lead patients to choose less healthy lifestyles – the more general health benefits that make following lifestyle advice important should not be lost.

References:

1. **Anon The management of dyspepsia in primary care MeReC Briefing 2006: Issue 32**
2. **Anon New Drugs from old Drug Ther Bull 2006; 44: 73-77**
3. **Management of dyspepsia in adults in primary care NICE Clinical Guideline No 17 August 2004**
4. **McKeage K et al Drugs 2008; 68: 1571-1607**