AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Nexium capsules
ACTIVE INGREDIENT: Esomeprazole Magnesium Hydrate

Study No: D961HC00011
NCT01435525

Developmental Phase: post-marketing
Study Completion Date: March/2014
Date of Report: July/2014

OBJECTIVES:

The objectives of the S-CEI were to investigate efficacy, development of ADRs, factors which may impact efficacy, and factors which may impact safety in patients given triple therapy for *H. pylori* eradication with Nexium + amoxicillin (AMPC) + clarithromycin (CAM), or Nexium + AMPC + metronidazole (MNZ) in usual post-marketing use.

METHODS: Observational Study

RESULTS:

1. Safety
In 352 patients of the safety analysis set, 14 events of ADRs were observed in 12 patients (3.4%) All patients who experienced ADRs were those given the first line eradication therapy: no patients experienced ADR during the second line eradication therapy.
The ADRs developed in at least 3 patients were diarrhoea in 7 patients (2.0%) and dysgeusia in 3 patients (0.9%): all the events were non-serious. The ADR unexpected from the Nexium JPI was polymyalgia rheumatica in one patient (0.3%). As causality between the event and a concomitant disease was suspected, and the number of patient who experience the event was only one, no new action is considered required for these events.
Fracture, community acquired pneumonia, and enterocolitis in association with *clostridium difficile* infection were the events which had been considered possibly related

to PPIs, and safety information for which should be collected after marketing. No patient experienced these events in the S-CEI.
The background factors and treatment factors in which significant difference ($p < 0.05$) was identified in ADR frequencies were drinking habit Yes vs. No (p=0.0488), dose change during triple therapy for *H. pylori* eradication Yes vs. No (p=0.0341), and discontinuation of triple therapy for *H.pylori* eradication Yes vs. No (p=0.0341). There was no issue which may require a new action.

2. Efficacy
The eradication rates after triple therapy for *H.pylori* eradication were: 81.4% (232/285) in the first line eradication therapy and 83.9% (26/31) in the second line eradication therapy. Efficacy of Nexium was confirmed because the rate was within the *H.pylori* eradication rate specified in "Guideline for diagnosis and treatment of *H.pylori* infection" (2009) by Japanese Society for *Helicobacter* Research, and the rate was similar to the rate confirmed in the data including clinical studies of omeprazole which is the racemic compound of esomeprazole.
The background factors and treatment factors in which significant difference ($p <0.05$) was identified in the eradication rates were the drinking habit Yes vs. No (p= 0.0193) in the first line therapy, and the smoking habit Yes vs. No (p=0.0067) in the second line therapy. There was no issue which may require a new action.
In view of these results from this S-CEI, there was no issue which may require a new action for the safety and efficacy of the triple therapy for *H.pylori* eradication in the usual post-marketing use.