AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Omepral® tablet 20, 10
ACTIVE INGREDIENT: Omeprazole

Study No: NIS-GJP-DUM-2007/1
Omepral® Tablets Special Clinical Experience Investigation in Patients with Erosive Esophagitis (OMAREE) – Interim Results -

Developmental phase: Post Marketing Surveillance
Study Completion Date: 1st Dec, 2009 (Final report completion)
Date of Report: 19th June, 2009 (Interim report)

OBJECTIVES:

Primary objective:

- To compare the efficacy of Omepral® tablet (Omepral® tablet 20 and 10 which includes omeprazole 20mg and 10mg as active ingredient, respectively) and any other treatments excepting proton pump inhibitors (PPIs) for the treatment of various type of acid reflux related symptoms in patients with reflux esophagitis

Secondary objective:

- To evaluate patient reported outcome from the treatment with Omepral® tablet or any other treatments excepting PPIs using QOLRAD-J
- To document epidemiology of acid related symptoms in the patient with reflux esophagitis

METHODS:

Eligible patients fulfilled the all inclusion criteria and not matched any of the exclusion criteria were assigned to either Group 1(Omepral® tablet) or Group 2 (any treatments other than PPIs). Investigators were requested to assign Group 1 and Group 2 by ratio of 4:1. Investigators decided dose of omeprazole, 20mg/day or 10mg/day according to medical condition of patient. All of the patients were registered at the central registration center.

At the start of the survey, 4, and 8 Weeks, investigators implemented interview about symptoms and asked patients to fill the questionnaires (QOLRAD-J and predefined patient reported symptom questionnaire) at the site.

The investigators recorded all of adverse events in Omepral® tablet group (Group 1) during the study period.

RESULTS:

10,731 patients were registered in this survey, of which interim analysis of 6,853 patients was completed. It consisted of 5,366 patients in Omepral® tablet group (Group 1) and 1,487 patients in other treatment group (Group 2). 92 % of patients were administered H2-receptor antagonists in Group 2.

46 % of the patients were elderly with age over 65 years. The ratio of gender, female: male was 58:42. The median of body mass index was 22.90. The most frequent GI symptom was heavy feeling in the stomach followed by feeling that sour contents are coming up from the stomach and belching. 76% of patients reported 3 or more symptoms and 32% reported 6 or more symptoms. Sufficient symptom improvement rates at 4 weeks were 61 % in Omepral® tablet group and 45% in other treatment group. The respective rates at 8 weeks were 82 % and 64%.

The mean QOLRAD-J score of all patients at the entry was 5.14. The most decreased score in each domain was vitality followed by food/drink problems. The score decreased with the increase of severity of symptom, days having symptom per week and number of patients' reported symptoms. The mean score at 8 weeks increased from 5.13 to 6.63 in Omepral® tablet group and from 5.21 to 6.32 in other treatment group, respectively.

Adverse drug reactions in Omepral® tablet group were observed in 42 (0.80%) out of 5,261 patients in the safety analysis data set. Two serious adverse drug reactions were reported, one was Vertigo (0.02%) and the other one was Blood pressure increased (0.02%). The most commonly reported adverse drug reactions were Gastrointestinal disorders (14 out of 5,261 patients (0.27%)), mainly comprised of Diarrhoea(0.10%) and Abdominal distension(0.06%) and Skin and subcutaneous tissue disorders (12 out of 5,261 patients (0.23%)), mainly comprised of Drug eruption (0.08%), Eczema (0.06%), Rash (0.06%).