

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No predefined treatment (any GERD treatment)

ACTIVE INGREDIENT: No predefined treatment (any GERD treatment)

Study No: NIS-GCH-NEX-2007/1

GERD Segmentation - Reflux disease: understanding it better

Developmental phase: Observational (non-interventional)

Study Completion Date: 12 August 2008

Date of Report: 9 January 2009

OBJECTIVES:

The main objective of this open, retrospective non-randomized non-interventional study was to assess how Swiss general practitioners allocate their GERD patients in the three patient-segments defined by King et al. and how treated GERD patients are affected by their GERD treatment by evaluation of symptom-induced impairments.

METHODS:

Open, retrospective non-randomized and non-interventional study. The general practitioner included all patients consulting for GERD within a given week, irrespective of the treatment received or prescribed (GERD treatment for at least 2 weeks before inclusion). The choice of GERD treatment was completely free to the investigator. Patient medical history was consulted for diagnosis date, symptomatology and treatment.

Adverse events were reported to the regulatory authorities according to the local legislations and forwarded to AstraZeneca's patient safety.

RESULTS:

Data from 2912 patients was available and entered in the database. All patients had a diagnosis of GERD and had received a treatment. No patient segment was available for 121 (4.2%) of the 2912 patients with available data. These 121 patients were excluded, leaving 2791 patients for the analysis.

The overall mean age was 57.8 ± 16.2 . The proportion of males was 48.3% for 51.1% of females (missing information for 0.6%). Of the 2791 patients included in the analysis, 20.6% (576) were in patient segment "long-term disrupting GERD", 33.1% (925) in patient segment "recurrent distressing GERD", and 46.2% (1290) in patient segment "inconveniencing GERD".

There were no serious adverse events reported. Three non-serious adverse events were reported. Two events (dizziness and pain due to drug interaction) occurred with Esomeprazole, and one event (gynecomastia) with Omeprazole.