AstraZeneca

STUDY REPORT SYNOPSIS

Finished product: not applicable

Active ingredient: not applicable

Study No. NIS-GAL-NEX-2010/1

A National, Multicentre, Open-label, Non-comparative, Non-interventional survey examining the frequency and severity of acid related symptoms while taking Nexium

Developmental phase: IV (non-interventional study)
Study completion date: 10 November 2010
Date of Report: 07 October 2011

OBJECTIVES:

The primary objective of this NIS was to evaluate the effectiveness of Nexium at alleviating frequency and severity of acid related symptoms.
Secondary objectives of the NIS were:

1. To follow the frequency, type and severity of symptoms in subjects consulting the doctors with upper GI symptoms.
2. Evaluate with which treatment regimen and on which indications acid suppression with isomeric proton pump inhibitor is used in routine clinical practice in Albania.
3. Evaluate the tolerability of Nexium in patients with upper GI symptoms.

METHODS:

Patients had three study related-visits: visit 1 (day 0), visit 2 (2-4 weeks after visit 1) and visit 3 (8-12 weeks after visit 1). At each visit the following tools were used: recording of data in CRF (by investigator) and filling in the Patient's questionnaire.

RESULTS:

Demographic data
The study was conducted in 26 centers with the participation of 37 Gastroenterologists and Endoscopists. They included a total of 484 patients in the study. The average age of patients included in the study was 46.5 years ± 15.7
The major part of the patients included were males (55.4 %). From the recorded habits the most common was the habit of smoking (28.1 %) even if the most part of them were non-smoker (68.2%). A small percentage 6.4 % had the habit of consuming alcohol more

than 2 units/day, 22.3 % less than 2 units/day and the major part of the patients included were non-alcoholists.

The frequency and severity of acid related symptoms:

All symptoms typically improved at visit 2 vs visit 1 and at visit 3 vs visit 2 and 1, based on the evaluation of the Gastroenterologists:

- The frequency and severity of pyrosis decreased substantially and linearly from the first visit to the third visit.
- The frequency and severity of regurgitation decreased considerably and linearly from the first visit to the third visit
- The frequency and severity of epigastric pain declined enormously and linearly from the first visit to the third visit
- The frequency and severity of pain or uncomfortable feeling in the stomach declined considerably and linearly from the first visit to the third visit
- The frequency and severity of dysphagia decreased from the first visit to the third visit
- The frequency and severity of nausea declined considerably and linearly from the first visit to the third visit
- The frequency and severity of sore throat or cough declined enormously and linearly from the first visit to the third visit

The prevalence of patients' self-reported complaints decreases sharply form the first visit to the second visit, and particularly so from the second visit to the third visit.

In the third visit:

The frequency of waking up due to GI symptoms was occasionally in only 2 % of the cases; the frequency of affecting patient's daily activities was occasionally in 6 % of the cases; frequency of taking bicarbonates or other symptomatic treatments was occasionally in only 0.2 % of the cases.

Treatment regimen and indications:

About 36 % of the patients had a history of more than a year with GI symptoms. More than half (55,8 %) were treated for GERD, 26.4 % for the presence of Helicobacter Pylori and the other percentage for other reasons.

The Nexium dose 20 mg was much more prevalent in the first visit (58,7 %) so in the second (69.2%) and the third visit (84.1%).

The treatment regimen in the third visit differed significantly from the treatment regimen in the second visit: more patients take Nexium as needed in the third visit (13.6%) compared with the second visit (0.6%)

Tolerability:

Nexium was very well tolerated. No adverse events were reported.