AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: None
ACTIVE INGREDIENT: None

Study No: NIS-GES-DUM-2008/2
Compliance of Gastroprotection Treatment in the Prevention of Gastrointestinal Risk in Non-Steroidal Anti-Inflammatory Drug (NSAID) Using Patients (GADES).

Developmental phase: Phase IV
Study Completion Date: 16 Jan 2009
Date of Report: 10 Dec 2009

OBJECTIVES:

Primary objective: To evaluate the compliance of gastroprotective treatment in NSAID patients at risk of GI complications.
Secondary objectives: To identify the factors associated to treatment compliance (both NSAID and PPI). To evaluate the relationship between compliance and NSAID-associated GI events.

METHODS:

Multicenter observational longitudinal study with prospective data collection. Adult patients with GI risk factors attending rheumatology/orthopedic clinics prescribed with NSAID + GP therapy for at least 15 days, were followed-up by phone calls at 15-60 days after prescription, by trained investigators with structured questionnaire. Exclusion criteria included patients on GP for reasons other than NSAID prevention. A multivariate logistic regression analysis was used to determine risk factors of adherence. A sample size of 1200 patients would provide an error < 3% for 50% levels of adherence.

RESULTS:

1. Low-dose, short-term NSAID and PPI co-therapy are the most common prescriptions issued in clinical practice in at risk patients.
2. Whereas most patients initiate NSAID therapy, over a fourth do not even start the GP agents.
3. Long-term treatment, co-therapy with anti-platelet agents and once daily therapy are predictors of adherence to this therapy.