

## STUDY REPORT SUMMARY

### ASTRAZENECA PHARMACEUTICALS

**FINISHED PRODUCT:** No drug

**ACTIVE INGREDIENT:** No drug

<b>Study No:</b> NIS-RSE-ATC-2011/1, NCT number NCT01519375
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Cross-sectional, observational Real Life study on NSAIDs treated patients with Osteoarthritis, Rheumatoid Arthritis and Ankylosing Spondylitis: Assessment of patient adherence to PPI treatment
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**Developmental Phase:** Observational study

**Study Completion Date:** 7 May 2012

**Date of Report:** 06 Mar 2013

#### OBJECTIVES:

The primary objective of this study was to assess patient reported adherence to PPI treatment on actual days of NSAID treatment. Secondary objectives were to assess proportion of patients with reported adherence  $\leq 80\%$  and to assess patient adherence to prescribed acetylsalicylic acid (ASA) treatment.

#### METHODS:

Patients with OA, RA or AS were identified in medical records and could be included in this multicentre, retrospective non-interventional study. The patients had to have current prescriptions of oral NSAID treatment and PPI for prevention of NSAID associated upper GI ulcers. Patients needed to have an instruction of PPI use on the same day as NSAID intake. Adherence was assessed for the past 7 days by a patient reported questionnaire. Only patients taking NSAIDs on at least 3 of the reported days could be included in the analyses.

#### RESULTS:

A total of 180 patients received a questionnaire; 134 completed and submitted it. A total of 96 patients (69% females, mean age 67 years) fulfilled all inclusion criteria. Of these, 72% had a diagnosis of OA, 16% RA and 12% AS. In all, 39% had a medical record history of dyspepsia and 22% a history of GERD. The three most common NSAIDs were diclofenac (34%), naproxen (24%) and ketoprofen (20%). Most common PPI was omeprazole, prescribed to 94% of the patients. Mean patient reported adherence of co-prescribed PPI when taking NSAID was between 73% and

81%. The proportion of patients with a patient reported adherence  $\leq 80\%$  was 26%. Adherence differences between high and low dose, type of NSAID drug, gender and disease were tested but no significant differences were detected. It was not possible to define patient characteristics predicting low adherence to co-prescribed PPI-treatment. 16 patients also had a concomitant prescription of low dose ASA. Mean patient reported adherence to co-prescribed ASA was 100%.