SYNOPSIS

Name of Sponsor/Company:	Janssen-Cilag, S.A.
Name of Finished Product:	Rabeprazole sodium
Name of Active Ingredient(s):	Rabeprazole sodium

Protocol No.: CR009238

Title of the study: Safety of rabeprazole in patients under multiple treatments.

Coordinating Investigator(s): Dr. Nieto

Publication (Reference): None (abstract in local congress)

Study Initiation/Completion Dates: 09 January-02/ 22 November 2002	**Phase of Development:** 4

Objectives: The aim of this study was the evaluation of PPIs (rabeprazole) safety in patients under multiple treatments.

Methodology: This was an observational, multi-centre, open and prospective study. Clinical profile of patients prescribed PPIs (rabeprazole) plus other drugs (one or more) was collected. Other prospective collected data were the following: demographic data, clinical history, co morbidities, concomitant treatment and the indication of rabeprazole.

Number of Subjects (planned and analyzed): 2157 patients were finally eligible to participate and were including in the safety analysis.

Diagnosis and Main Criteria for Inclusion: Males and females ≥ 18 years of age, receiving rabeprazole and a any other concomitant drug (one or more)

Test Product, Dose and Mode of Administration, Batch No.: This was a descriptive studied carried out according to the general clinical practice. Therefore, no intervention in the prescribed drugs was performed

Reference Therapy, Dose and Mode of Administration, Batch No.: Non applicable.

Duration of Treatment: Study period: 6 weeks

SYNOPSIS (CONTINUED)

Criteria for Evaluation:
The use of rabeprazole plus concomitant drugs prescribed in clinical practice was evaluated by descriptive statistics. Adherence and compliance with treatment, lifestyle (smoking and alcohol consumption) and dose of rabeprazole were evaluated. Safety analysis based on elicited adverse events was also performed.

Statistical Methods: Effectiveness and safety results were analyzed using descriptive statistic. SPSS, version 8 was used to analyze the data.

SUMMARY – CONCLUSIONS
Smoking habit: 63% non-smoking, 26% occasional smoking, 8% usual smoking and 3% data no available.
Alcohol consumes: 57% non-alcohol use reported; 43% moderate consume.
Concomitant treatments: the most common concomitant treatments prescribed plus PPIs (rabeprazole) were NSAIs (56%), corticoids (11%) and diazepam (8%). The indications of the concomitants treatments were arthrosis (21%), lumbar pain (7%) and hypertension (6%). A group of 70 patients (3%) used a concomitant

therapy for treating a tumor. Reasons for prescribing PPIs (rabeprazole): 20% of the patients gastro esophageal reflux, 12% dyspepsia. The protection of gastric mucosa was also other indication for PPI treatment.
Mean dose of rabeprazole was 20 mg/day. There was not found a different dose prescription in the different diseases (oncology / non-oncology). Adherence to treatment was evaluated by CGI scale in basal and final visit. Patients of all groups were adherent to rabeprazole and other treatments.
It wasn't observed different between smoking and alcohol consumption.
3% of patients undergoing fentanyl treatment needed an adjustment of the treatment.
2% of the patients experienced adverse event. 0.5% (n=10) experienced AEs related with rabeprazole (20mg/day), mainly diarrhea and headache.

SYNOPSIS (CONTINUED)

CONCLUSION:

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Date of this report: 12 june 2007

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