Clinical Study Synopsis for Public Disclosure

This clinical study synopsis is provided in line with **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

The synopsis - which is part of the clinical study report - had been prepared in accordance with best practice and applicable legal and regulatory requirements at the time of study completion.

The synopsis may include approved and non-approved uses, doses, formulations, treatment regimens and/or age groups; it has not necessarily been submitted to regulatory authorities.

A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country.

Additional information on this study and the drug concerned may be provided upon request based on **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

2. SYNOPSIS

Name of company: Boehringer Ingelheim Promeco		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Mobicox				
Name of active ingredient: Meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:** I	**Page:** 1 **to** 32		**Addendum No.:**
Report date: 13-December-2004	**Number:** U04-3561	**Study period (years):** 1 year		

Title of study:	Programa de Experiencia Terapéutica Personalizada (Personalized Therapeutic Experience Program)
Investigator:	[redacted]
Study center(s):	Multicentre.These booklets were distributed to treating physicians by our Sales Force
Publication (reference):	N/A
Clinical phase:	IV PMS
Objectives:	Evaluation on the amelioration of symptom intensity of the indication and to evaluate drug tolerability.
Methodology:	A 12 months observational study performed by Mexican Physicians that prescribed Meloxicam to their patients for any labeled indication
No. of subjects entered:	13,039
total:	13,039
each treatment:	10 patients per physician
Diagnosis and main criteria for inclusion:	PMS Inclusion of patients according to the physicians medical criteria on the labeled indications for Meloxicam
Test product:	Meloxicam
dose:	Tablets 7.5 mg and 15mg as well as injectable solution 15mg.
mode of admin.:	Oral/Itramuscular injection
batch no.:	
Duration of treatment:	According to medical judgement and base disease
Reference therapy:	N/A
dose:	N/A
mode of admin.:	N/A
batch no.:	N/A
Criteria for evaluation:	
Efficacy:	A change in the verbal scale for pain from 1 grade to another of lower value
Safety:	All AEs were collected and data compared with the Meloxicam BPI
Statistical methods:	Descriptive analysis with central tendency measurements

SUMMARY - CONCLUSIONS:

Efficacy results:	The patients completed the treatment 99.56% of the times, and the final intensity of pain was mild in 20.37% of cases, moderate in 8.17%, severe in 1.09%, and no pain in 46.34% of the cases and in 3,337 of the cases the physicians did not report the final status of their patients. Treatment duration with Meloxicam was less than 35 days in 56.22% of the 13,039 patients and in 6.5% was more than 35 days. In 37.27% treatment duration was not specified.
Safety results:	We found a total of 477 adverse events in 375 patients (2.88%), out of these only 7 were serious (0.05%), and the rest of them, 470 (2.82%) were not serious. The events were mostly from the gastrointestinal system in 2.63% of the cases, and women were more affected than men (F:M ratio 1.58: 1). Tolerability was reported as good or excellent in 75.56% of the cases.
Conclusions:	Meloxicam demonstrated an efficacy and tolerability comparable to that of the published literature, and this makes Meloxicam a reasonable first line drug for use in Mexican population for the treatment of the indications labeled in Mexico.