Boehringer Ingelheim

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		**Tabulated Trial Report**	Boehringer Ingelheim
Name of finished product: Mobicox			
Name of active ingredient: Meloxicam		**Page:** 1 of 2	**Synopsis No.: 1**
Module:		**Volume:**	
Report date: 23 May 2011	**Trial No. / U No.:** 107.264 / U11-3131-01	**Date of trial:** May 2003 – July 2004	**Date of revision** (if applicable)**:** Not applicable

Title of trial:	Clinical therapeutic evaluation program in patients with rheumatic diseases
Principal Investigator:	No principal investigator was appointed
Trial sites:	Multicentre study in Mexico
Publication (reference):	NA
Clinical phase:	IV PMS
Objectives:	Evaluate the efficacy and safety of meloxicam (Mobicox®) in Mexican population with rheumatic diseases.
Methodology:	Open observational study with descriptive analysis performed to evaluate the efficacy and safety of the drug in a heterogeneous Mexican population with rheumatic diseases.
No. of subjects: **planned:** **actual:**	12,687 12,687 NA
Diagnosis and main criteria for inclusion:	Mexican patients with ≥ 12 years with any of the recommended indications for meloxicam.
Test product:	Meloxicam
dose:	7.5, 15 mg./day
mode of admin.:	Oral, intramuscular injection
batch no.:	NA
Reference therapy:	NA
dose:	NA
mode of admin.: **batch no.:**	NA NA

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Duration of treatment:	Observation period up to 90 days
Criteria for evaluation:	Efficacy and safety
Efficacy / clinical pharmacology:	Intensity of the symptoms measured with a four points scale. Degree of satisfaction evaluated with a six point numerical rating scale.
Safety:	All AE reported during the study were collected.
Statistical methods:	Descriptive statistics

SUMMARY – CONCLUSIONS:

Efficacy / clinical pharmacology results:	From the 12,687 patients included in this study, 10,012 (78.9%) of them experienced relief of their symptoms at rest and 10,404 (82.0%) during movement after 30 days on treatment. Medical global evaluation considered a good performance of the treatment in 84.9% of the patients. Only 5,426 patients (42.8%) were followed up after 90 days and 4,999 of them experienced relief of the symptoms at rest and 5,048 during movement with meloxicam. In the medical global evaluation, most of them, 83.7%, had a good performance of the drugAn excellent degree of satisfaction at the end of the treatment was obtained of 8,725 patients (68.8%), 2,334 patients (18.4%) reported a good degree of satisfaction.
Safety results:	203 patients (1.6%) experienced at least 1 AE. From a total of 255 AEs, 12 of them (4.71%) were SAE and 243 (95.29%) were not serious.
Conclusions:	Under actual prescribing in Mexican population, meloxicam (Mobicox®) showed an adequate efficacy and a favorable safety profile.