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 4	**Synopsis No.: 1**
Module:		**Volume:**	
Report date: 13 June 2011	**Trial No. / U No.:** 107.272 / U11-3237-01	**Date of trial:** January 2004 – April 2007	**Date of revision** (if applicable)**:** Not applicable

Title of trial:	Clinical and therapeutic evaluation of Meloxicam in Mexican patients with rheumatic diseases
Coordinating Investigator:	[redacted]
Trial sites:	Multicentre study in Mexico
Publication (reference):	NA INFORMATION NOT AVAILABLE
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:	22,639
planned:	22,639
actual:	NA INFORMATION NOT AVAILABLE
Diagnosis and main criteria for inclusion:	Inclusion of Mexican patients with rheumatic diseases according to the physicians medical criteria on the labeled indications for meloxicam (Mobicox®)

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Test product:	Meloxicam
dose:	7.5, 15 mg./day
mode of admin.:	Oral, intramuscular injection
batch no.:	NA INFORMATION NOT AVAILABLE
Reference therapy:	NA INFORMATION NOT AVAILABLE
dose:	NA INFORMATION NOT AVAILABLE
mode of admin.:	NA INFORMATION NOT AVAILABLE
batch no.:	NA INFORMATION NOT AVAILABLE
Duration of treatment:	Observation period up to 90 days
Criteria for evaluation:	Efficacy and safety
Efficacy / clinical pharmacology:	Decrease of the intensity of symptoms at rest and during movement evaluated with a 4 point scale by patients and through a medical global evaluation at 30 and 90 daysDegree of satisfaction was assessed with a visual analogous scale (VAS) at the end of the study
Safety:	All AE reported during the study were collected
Statistical methods:	Descriptive analysis with central tendency measurements and percentages. Percentages were calculated according the available total number of patients in every cut-off point (30 and 90 days)

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SUMMARY – CONCLUSIONS:

Efficacy / clinical pharmacology results: A total of 22,639 subjects were included. From 22,639 patients enrolled in the study, 20,119 patients (88.9%) and 12,557 (55.5%) were assessed after 30 and 90 days on treatment, respectively. There was a reduction in the highest levels of pain intensity during rest from baseline to 30 and 90 days, 24.4%, 15.0% and 2.9%, respectively. Despite there was a worsening of the highest levels of pain intensity during movement at 30 days comparing with baseline, at 90 days, there was a significant improvement, 10.7%, 19.4% and 3.2%, respectively. In total, 15,088 patients (66.6% of original group, 75% of available patients at 30 days) and 10,313 (45.5% of original group, 82.1% of available patients at 90 days) had improvement in their medical global evaluation at 30 and 90 days, respectively. Higher degrees of satisfaction with the treatment were reported by 20,150 patients (89.0%).

Safety results: From the 22,639 patients included in this study, only 348 patients (1.5%) had 455 adverse events. Most of them where mild and transitory. Twenty-five SAE were reported.

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Conclusions:

The aim of this PMS study was to evaluate the efficacy and safety profile of meloxicam (Mobicox®) in Mexican patients with rheumatic diseases during a 90 days period. The analysis at 30 days showed a significant relief of symptoms in rest (Very high and high intensity at baseline 25.6% versus very high and high intensity at 30 days 16.8%), but not during movement (Very high and high intensity at baseline 11.1% versus very high and high intensity at 30 days 21.9%). The analysis at 90 days found more relief of the symptoms in rest (Very high and high intensity at baseline 25.6% versus very high and high intensity at 90 days 5.1%) than in the previous analysis, and during movement (Very high and high intensity at baseline 11.1% versus very high and high intensity at 90 days 5.9%). This means that continuing the therapy with meloxicam (Mobicox®) was associated with an improved symptomatic patient response. In addition to this, it was observed that the patients experienced a high degree of satisfaction (89.0%) with the drug at the end of the treatment. Physicians scoring the drug as good in 66.7% of the cases (considering the results of the patients on scale 1 and 2 from the 4 point scale) in the interim analysis and good in a 45.5% of the cases (also considering the results on scale grade 1 and 2 from the same scale) in the final analysis. Regarding to safety, only 348 patients (1.5%) from the 22,639 studied patients reported at least one AE. Frequency of AE reported was similar to previous reported series.