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***.

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U01-3301

2. SYNOPSIS

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: MOBIC®				
Name of active ingredient: UH AC 62 XX, Meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:** xxx **to** xxxx		**Addendum No.:**
Report date: 26 September 2001	**Number:** U01-3301	**Study period (years):** 28 October 1998 to 16 November 2000		

Title of study:	A Multi-Center, Randomized, Parallel-Group, Open-Label Study to Compare Prescription Non-Steroidal Anti-Inflammatory Drug (NSAID) Changes, Health Care Utilization, Efficacy and Safety of Meloxicam 7.5 mg versus Usual Care Administration of Prescription NSAIDs in a Managed Healthcare Setting in Patients with Osteoarthritis of the Hip, Knee, Hand or Spine
Investigator:	Multicenter study without official designation of a Principal or Coordinating Investigator, see Section 6 and 16.1.4
Study center(s):	Multicenter study without official designation of a Principal or Coordinating Investigator, see Section 6 and 16.1.4
Publication (reference):	Not Applicable
Clinical phase:	IIIb
Objectives:	To compare the percentage of treatment successes or failures in patients randomized to meloxicam 7.5 mg vs. usual care prescription NSAIDs. Additionally, health care utilization, efficacy and safety of patients in a managed healthcare setting with osteoarthritis (OA) of the hip or knee will be assessed.
Methodology:	Multi-Center, Randomized, Parallel-Group, Open-Label Comparison
No. of subjects entered: **total:** **each treatment:**	1323 1309 treated 662 in meloxicam arm; 647 usual care arm
Diagnosis and main criteria for inclusion:	Patients at least 18 years of age with a documented history of OA of the hip, knee, hand or spine for whom prescription NSAID therapy was indicated. Patients must be members of a selected managed care organization.
Test product: **dose:** **mode of admin.:** **batch no.:**	Meloxicam 7.5 mg once per day, with possible dose escalation to 15 mg once per day Administered orally between 6 am and 9 am, after food and with a glass of water PD 1843

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Duration of treatment:	Six months
Reference therapy:	Usual Care Prescription NSAID
dose:	Within approved labeling recommendations for OA
mode of admin.:	Within approved labeling recommendations for OA
batch no.:	N/A
Criteria for evaluation:	
Efficacy:	Percentages of Treatment Successes, Time to Permanent Discontinuation of the 1st NSAID, Time to Permanent Discontinuation of the 1st NSAID due to Lack of Efficacy, Number of NSAID Therapies during the Trial, Investigator's Global Assessment of Disease Activity, Patient's Overall Assessment of Pain over the Past Week, Patient's Assessment of Health Status, Patient's Assessment of Satisfaction of Health, Utility Index, Western Ontario and McMaster University Osteoarthritis Index (WOMAC), Disability Index, Patient's Satisfaction of Osteoarthritis Care, Satisfaction with Current OA Medication, Difficulty Swallowing OA Medication.
Safety:	Incidence and intensity of adverse events; withdrawals due to adverse events
Statistical methods:	Descriptive statistics, Exact permutation test, Kaplan-Meier Survival Curve Logrank Test, Wilcoxon Rank Sum Test, Analysis of Variance, Analysis of Covariance, Logistic Regression, Cox Regression, and Log-linear Regression.

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SUMMARY – CONCLUSIONS:

Efficacy results:

For all the primary and secondary efficacy endpoints, the meloxicam group showed significantly better results than the usual care group. In the endpoints that evaluated the NSAID prescription, the meloxicam group had a higher treatment success rate, a longer duration that patients stayed on the first NSAID, and fewer number of NSAID therapies compared with the usual care group.

In all the endpoints that evaluated the clinical effectiveness, the meloxicam therapy proved to be more efficacious than the usual care. For the eight endpoints that were measured at every month (patient's assessment of pain, patient's assessment of health status, patient's assessment of satisfaction of health, utility index, and WOMAC index as total, pain, stiffness, and physical function), the meloxicam group was more effective than the usual care group in both the last (using last observation carried forward (LOCF) and the average on 1st NSAID. The meloxicam group maintained its superiority even at the last (LOCF) and the average on study measures after more patients in the usual care group switched their failing initial NSAIDs for the majority of endpoints. For endpoints that were measured at baseline and at the end of the study (investigator's global assessment of disease activity and disability index), the meloxicam group had better improvements from baseline than the usual care group.

For endpoints that measured the patient's perception at Month 1 and Month 6 (patient's satisfaction of osteoarthritis care, satisfaction with current OA medication, and difficulty swallowing OA medication), the patients in the meloxicam group showed better appreciation of the therapy at Month 1 when most patients were on their 1st NSAID therapy.

This trial successfully evaluated the advantage of the meloxicam therapy related to NSAID prescription, clinical effectiveness, and patient's perception compared with the usual care therapy in the treatment of osteoarthritis patients in the managed care setting.

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Safety results:	This six-month trial showed meloxicam to be well tolerated. The incidence of adverse events was comparable in both treatment groups. The incidence of adverse events, serious adverse events, and adverse events related to study drug, occurred less frequently in the meloxicam arm, both while the patient was receiving meloxicam and during the patient's time in study. The overall incidence of adverse events was 69.2% for meloxicam patients and 72.3% in the usual care patients. Similarly, while on initial NSAID, 62.4% of meloxicam patients had an adverse event versus 63.2% of usual care patients. The severity of adverse events during the trial was similar in both treatment groups. Most of the events were mild in intensity accounting for 48.3% of meloxicam adverse events and 49.8% of usual care adverse events. Adverse events were less frequently reported as being related to study drug with 19.5% related in the meloxicam group and 25.2% in the usual care group. Patients who experienced adverse events leading to discontinuation from the study were less frequent in the meloxicam group with 16 (2.4%) compared to the usual care group at 20 (3.1%). Patients who experienced adverse events leading to discontinuation of first NSAID were also less frequent in the meloxicam group at 76 (11.5%) versus 131 (20.2%) in usual care. A review of PUBs, irrespective of the clinical significance, revealed four patients in the meloxicam group and three patients in the usual care group experienced a PUB while on their first NSAID. Of the four patients in the meloxicam group, three patients discontinued the meloxicam due to the adverse event and one continued meloxicam during the event. Of these four patients, two patients completed trial participation, one patient withdrew consent and one patient discontinued participation early due to an adverse event. Of the three patients in the usual care group who experienced a PUB, all patients discontinued their NSAID due to the event and completed trial participation.

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Conclusions:	• Meloxicam had significantly more successes than usual care NSAIDs over six months, and was well tolerated. • Patients were significantly more satisfied with meloxicam, as demonstrated by successes compared with usual care prescription NSAIDs. • The results of the success tended to cluster around the three most recently approved NSAIDs, meloxicam, celecoxib, and rofecoxib. • Meloxicam was shown to be effective in treating the symptoms of OA in that patients on meloxicam had greater efficacy than in the usual care group. • There were significantly fewer patients experiencing AEs in the meloxicam group compared with the usual care group when adjusted for difference in first NSAID exposure time. • The AE results seen for meloxicam are consistent with those of double blind comparative studies for GI tolerability profile.