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**.

Name of company: Boehringer Ingelheim International GmbH		**Tabulated Study Report**	Boehringer Ingelheim
Name of finished product: Mobic®			
Name of active ingredient: Meloxicam		**Page 1 of 3**	
Report date: 23 May 2005	**Trial Number:** 107.265	**Study period (dates):** Jul 2004 to Dec 2004	**Date of Revision**

Title of study:	A randomised, open-labelled study to compare the efficacy and safety of meloxicam 7.5 mg IM ampoules once daily and meloxicam 7.5 mg tablets administered orally once daily over a period of 7 days in patients with osteoarthritis (OA)
Investigator:	[redacted]
Study center(s):	Multicentre trial: 7
Publication (reference):	none
Clinical phase:	III
Objectives:	Safety and efficacy of meloxicam 7.5 mg i.m. ampoule once daily compared with meloxicam 7.5 mg tablets orally once daily over a treatment period of 7 days
Methodology:	Randomised, open-labelled, two groups comparison
No. of subjects entered: **total:** **each treatment:**	168 168 84
Diagnosis and main criteria for inclusion:	Acute exacerbation of Osteoarthritis (pain rated ≥ 40 mm on a VAS) of hip and knee
Test product: **dose:** **mode of admin.:** **batch no.:**	Meloxicam Ampoules 7.5 mg Intramuscular B040306
Duration of treatment:	7 days
Reference therapy: **dose:** **mode of admin.:** **batch no.:**	Meloxicam Tablets 7.5 mg Oral 384009

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Criteria for evaluation:	*Primary endpoint*: Pain on active movement. *Secondary endpoints*: pain at rest, patient's assessment of arthritic condition, patients status with regard to change of arthritic condition, final global efficacy, withdrawals due to inadequate efficacy, paracetamol consumption, onset of action, time to maximum pain relief, patient's and investigator's assessment of local tolerability, patient's and investigator's assessment of overall tolerability, withdrawals due to safety reasons, change in other laboratory investigations, number, nature and severity of adverse events.
Statistical methods:	An ITT and PP analysis of the data from all patients treated according to the protocol were performed. Continuous efficacy parameters were evaluated by ANCOVA, categorical efficacy parameters were evaluated by Wilcoxon test or non parametric tests for contingency tables. Incidence, severity and causal relationship of the adverse events was tabulated by body system organ class.

SUMMARY – CONCLUSIONS:

168 out of 169 randomised and treated subjects were included in the efficacy and safety analysis (intent-zo-treat analysis). No explanatory analysis was performed.

Efficacy results:	Meloxicam 7.5 mg ampoules and 7.5 mg tablets were effective in this seven days OA-trial. The observed parameters improved significantly during the course of therapy in both treatment groups. There was no statistical significance between the two treatments in terms of the primary endpoint i.e. pain on active movement. The analysis of the secondary endpoints also showed no significant differences. The 95 % CI of the reduction from the baseline value between 2 treatments on primary endpoints is – 7.20 mm to 1.30 mm. As predefined in the protocol, the equivalence margin is 7.5 mm. The 95 % CI of the reduction from the baseline value between 2 treatments hadn't exceeded the equivalence margin, it could be concluded that the efficacy of meloxicam ampoules group is noninferior to that of meloxicam tablets groups.

Safety results:	Both treatment groups were found to be safe and well tolerated. 14 patients (16.67 %) in the meloxicam 7.5 mg ampoules group, and 8 patients (9.52 %) in the meloxicam 7.5 mg tablets group experienced at least one adverse event. The type and frequency of the adverse events were similar in both active treatment groups. The most frequent adverse event in the meloxicam 7.5 mg ampoules group was caused by the injection. For the meloxicam 7.5 mg tablets group, it was disorders of the gastrointestinal system. No serious adverse event was reported. Only 1 patient in the meloxicam 7.5 mg ampoules group was withdrawn for adverse events during the trial. The patient was from the ampoules group, who suffered by moderate dizziness and chest distress. And the symptoms were considered drug-related by the investigator. There was no significant difference regarding rate of withdrawals due to adverse events between the two treatment groups. Overall the tolerability was assessed either as good or statisfactory by the investigators (98.8 % of the cases in the meloxicam 7.5 mg ampoules group, and 98.8 % of the cases in the meloxicam 7.5 mg tablets group). When it was self assessed by the patient, 97.56 % of them evaluated it as good or statisfactory in the group treated with meloxicam 7.5 mg ampoules and 100 % of the patients treated with meloxicam 7.5 mg tablets.
Conclusions:	The efficacy of meloxicam 7.5 mg ampoules is noninferior to that of meloxicam 7.5 mg tablets. Both meloxicam routes of administration studied in this short term OA trial were safe and well tolerated with a comparable severity and incidence of adverse events. This trial confirmed that the local tolerability of the im route of meloxicam was good. It was concluded that meloxicam 7.5 mg ampoules was as effective and comparably safe as meloxicam 7.5 mg tablets in short term treatment of patients with osteoarthritis, and therefore can be considered as an alternative to the tablets during the initial course of disease.