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***.

4. SYNOPSIS

Name of Company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Mobic®				
Name of active ingredient: Meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:** to		**Addendum No.:**
Report Date: February 21, 2000	**Number:**	**Study Period:** Apr. 1999 – Nov. 1999		

Title of Study:	Open label study to assess the efficacy and safety of Meloxicam 7.5mg vs. Diclofenac 100mg in patients with osteoarthritis of the knee
Investigator:	[redacted]
Study center(s):	[redacted]
Publication (reference):	None
Clinical phase:	IV
Objectives:	To assess the efficacy and safety of meloxicam 7.5mg once daily compared with diclofenac 100mg SR once daily over a treatment period of 8 weeks
Methodology:	Open –label, randomised, comparative, multicenter trial
No.of subjects entered: **Total:** **ITT analysis (PP analy.)**	101 screened 91 treated 80 analysed (PP analy. 72)
Diagnosis and main Criteria for inclusion:	Osteoarthritis of the knee requiring the therapy with non-steroidal anti-inflammatory drugs(NSAIDs)
Test product: **Dose:** **Mode of admin.:**	Meloxicam 7.5mg Oral
Duration of treatment:	56 days (8 weeks)
Reference therapy **Dose :** **Mode of admin. :**	Diclofenac 100mg Oral

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Criteria for evaluation:

Efficacy: **Primary endpoints:** pain on active movement by a 100mm visual analogue Scale (VAS)

Efficacy: **Secondary endpoints:** Lequesne index, global assessment by the patient and doctor

Safety: incidence of adverse events, laboratory findings, physical examination

Statistical methods: Principally Intent-to-treat analysis and Per protocol analysis
Efficacy: ANCOVA, paired t-test, unpaired t-test, extended Mantel-Haenszel mean score statistic
Safety: Fisher's exact test

SUMMARY – CONCLUSIONS:

Efficacy :

Mean change in pain on active movement was –25.0±18.5mm and –19.0±18.2mm in the meloxicam and diclofenac group respectively, which were statistically significant from baseline (p=0.0001).

Regarding Lequesne index, there was an improvement in meloxicam and diclofenac group of –3.8±3.1 and –3.1±3.9 respectively, which were statistically significant from baseline(p=0.0001). No statistically significant differences of efficacy parameters were observed between treatment groups. Global efficacy assessed by the patient and doctor at the end of study was slightly in favor of meloxicam, but there was no statistically significant differences between the groups.

Safety:

While 34 patients (73.9%) in diclofenac group, 17 patients (37.8%) in meloxicam group experienced at least one adverse event. Drug-related AEs were 11(24.4%) and 23(50.0%) in meloxicam and diclofenac group. Significant differences showed between groups. 1 patient and 2 patients were discontinued due to adverse events in the meloxicam and diclofenac group. No death or SAE were found in this trial.

Conclusion:

Meloxicam 7.5mg is as effective as diclofenac 100mg in patients with acute symptomatic osteoarthritis of the knee. Meloxicam 7.5mg has a safety advantage e.g. less frequent total AEs than diclofenac 100mg.