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: July 29, 1999	**Number:**	**Study Period:** Oct. 1998 – Feb.1999		

Title of Study:	Open study to assess the efficacy and safety of meloxicam 7.5mg 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 over a treatment period of 56 days
Methodology:	Open
No.of subjects entered: **Total:** **ITT analysis (PP analy.)**	36 screened 30 treated 23 (21) analysed
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)

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Criteria for evaluation:	**Primary endpoints:** pain on active movement by a 100mm visual analogue Scale (VAS)
Efficacy:	**Secondary endpoints:** Lequesne index, physical examination (tenderness, swelling)
Safety:	Endoscopy, GI symptoms score , laboratory findings, incidence of adverse events
Statistical methods:	Principally Intent-to-treat analysis and Per protocol analysis Efficacy: Wilcoxon's signed rank test, McNemar's test Safety: McNemar's test, Wilcoxon's signed rank test, paired t-test

SUMMARY – CONCLUSIONS:

Efficacy :

Mean change in pain on active movement between baseline and after treatment was 33.2mm (Mean ± SD : Baseline 59.5±19.9mm, After 8weeks 26.3±15.8mm, p=0.0001).

Regarding Lequesne index, mean change of total score is 2.7 (Mean ± SD : baseline 7.7±3.8 score, after 8 weeks 5.0±3.6 score, p=0.0001). Therefore, there was statistically significant improvement on pain on active movement & functional disorders through treatment of Mobic 7.5mg during 8 weeks.

Tenderness was improved significantly, but no statistically significant difference was observed in swelling.

Safety:

Total 9 adverse events were reported in 7 patients and among them, 2 patients withdrew the informed consent due to adverse events. Edema/dry mouth occurred in 1 patient were drug-related and 1 patient was discontinued due to cold. Among 9 adverse events, 5 AEs were related to GI system.

No significant difference was observed in endoscopy & GI symptoms from baseline.

Gastric ulcer was occurred in one patient with current erythematous/ exudative, atrophic gastritis.

There was no clinically significant finding in laboratory result.

Conclusion:

Meloxicam 7.5mg is effective in patients with acute symptomatic osteoarthritis of the knee.

There was no significant difference from baseline in safety variables (endoscopy, GI symptoms, lab. test).

9 AEs occurred in 7 patients and 2 patients withdrew due to adverse event.