Clinical Study Synopsis for Public Disclosure

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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***.

CLINICAL TRIAL REPORT SUMMARY

Name of company: Boehringer Ingelheim International Trading(Shanghai) Co., Ltd. **Name of finished product:** Mobic® **Name of active ingredient:** Meloxicam		**Tabulated Study Report**	
Protocol date: Dec. 06, 2000	Trial number: 107.237	**Planned Study period:**	July, 2001—May, 2002
Title of study: A randomized, open label, 3-arm evaluation of efficacy and safety of Meloxicam suppository (15mg daily) and tablet (15mg daily) compared to Indomethacin suppository (50m5rg daily) in patients with ankylosing spondylitis			
Principal Investigators: [redacted]			

Study centre(s):	3
Publication:	no
Clinical phase:	IIIb
Objectives:	To assess the efficacy and safety of meloxicam suppository 15 mg, once daily, meloxicam tablet 15mg once daily compared with Indomethacin suppository (50mg daily) in patients with ankylosing spondylitis
Methodology:	Randomized, open-label, three arm compared study
No. of subjects **total:** **each treatment:**	 180 60
Diagnosis and main criteria for inclusion:	Active ankylosing spondylitis(pain rated ≥ 40mm on a VAS and increased of at least 30% after NSAIDs wash-out), without Peripheral arthritis and inflammatory bowel disease.
Test product 1: **dose:** **mode of admin.:** **batch no.:**	Meloxicam suppository 15mg mg rectal administration 033085A
Test product 2: **dose:** **mode of admin.:** **batch no.:**	Meloxicam tablet 15mg mg oral therapy 009047
Duration of treatment:	6 week
Reference therapy: **dose:** **mode of admin.:** **batch no.:**	Indomethacin suppository 50mg 50mg rectal administration 010201

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Criteria for efficacy:	Overall pain during the previous 48 hours assessed on a VAS, functional index of ankylosing spondylitis of Dougados, overall assessment of disease activity by the patient on a VAS, overall assessment of disease activity by the investigator on a VAS, global efficacy as assessed by the patient (verbal rating scale), global efficacy as assessed by the investigator (verbal rating scale), duration of morning stiffness, evaluation of spinal pain by the investigator (verbal rating scale), Schober test, chest expansion, fingers-to-floor test, night pain (verbal rating scale), total number of study withdrawals, number of study withdrawals due to lack of efficacy, paracetamol consumption, patient status with regard to disease condition		
Criteria for pharmacoeconomics:	Duration of hospital stay due to GI or any other drug-related event; visit to a physician due to GI-AE		
Criteria for safety:	incidence and intensity of adverse events, withdrawals due to adverse events, incidence of laboratory adverse events (liver, kidney, haematology), final global tolerability by patient and investigator		
Statistical methods:	Intent-to-treat and explanatory analysis for all parameters: Efficacy: t-test or Wilcoxon test, Fisher's exact test or Chi-square test, ANOVA or logistic regression, 95% confidence intervals will be given. Safety: tabulation by body system organ class, odds ratios between treatment groups, score analysis referring to normal ranges for laboratory parameters		
Summary conclusion:	All the 192 randomized and treated patients were included in the efficacy and safety analyses(intent-to-treat analyses). The rate of withdrawals during six weeks of the trial was higher in the indomethacin suppository group(12/66, 18.18%) than in the two meloxicam group: 3.13%(2/64) in the meloxicam tablet group and 6.45%(4/62) in the meloxicam suppository group and 15.7% in the Indomethacin group($P<0.005$). There is no statistically significant difference between meloxicam tablet and suppository groups. The efficacy analysis was performed with last values on treatment carried forward.		

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Efficacy:

Primary endpoints:

There was globally a treatment effect regarding each of the three primary endpoints (P<0.0001). With respect to the primary endpoints after 6 weeks treatment in 3 group. The efficacy of meloxicam 15mg tablet and meloxicam 15mg suppository was significantly better than indomethacin 50mg suppository (P<0.001). With no statistically significant difference between meloxicam tablet group and meloxicam suppository group.

The mean ± SD absolute decrease from baseline 74.4±12.6 mm to 21.7±16.6 mm in overall pain intensity in the meloxicam 15mg tablet group, 72.0±15.4 mm to 20.6±17.8 mm in the meloxicam 15mg suppository group, 70.7±14.1 mm to 36.3±21.4 mm in the indomethacin suppository group.

Regarding Dougados functional index, there was also a significant improvement in meloxicam 15 mg tablet group, meloxicam 15 mg suppository group than indomethacin 50 mg suppository group respectively. For meloxicam 15 mg tablet group, it changes from the baseline 15.0 ± 5.4 to 4.0 ±4.4 respectively, from baseline 13.0±5.5 to 3.7±3.9 in meloxicam 15 mg suppository group, and from baseline 12.6±6.7 to 6.9±6.7 in indomethacin suppository group.

The mean ± SD improvement in disease activity assessed by the patient was also a significant improvement in meloxicam 15 mg tablet group, meloxicam 15 mg suppository group than indomethacin 50 mg suppository group. It is from 68.3 ± 14.5 mm to 22.4 ± 18.4 mm in the meloxicam 15 mg tablet group, from 65.3± 16.6mm to 20.2 ± 15.7mm in the meloxicam 15mg suppository group, from 64.0 ± 18.8 mm to 34.6 ± 21.7 in the indomethacin suppository group.

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	Safety: Safety of the three active treatment groups was good: 21.87% (14/64)of treatment patients in the meloxicam 15 mg tablet group, 12.9% (8/62)in the meloxicam 15mg suppository group, 25.76% (17/66)in the indomethacin 50mg suppository group experienced at least one adverse event. 18.75%(12/64) of the patients in the meloxicam 15mg tablet group, 8.06% (5/62)in the meloxicam 15mg suppository group, 24.24%(16/66) in the the indomethacin 50mg suppository group had at least one adverse event which was classified by the investigator as possibly related to the study drug. Except the percentage of patients with at least one drug related adverse event in the meloxicam 15mg suppository group has statistically significant difference than those of the indomethacin 50mg suppository group($P<0.05$), there was no statistically significant difference regarding the percentage of patients with at least one adverse event and the percentage of patients with at least one drug related adverse event between the three treatment groups. As expected, gastrointestinal adverse events were the most common ones. There was no statistically significant difference between the three treatment groups regarding percentages of patients with gastrointestinal adverse events and drug related gastrointestinal adverse events. No serious adverse events were reported during the trial.		