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**	
Reporte date: 21 May 2003	**Trial-Number:** 107.245	**Study period (years):** May 2001 – Dec 2001	

Titel of Study:	COX-2 postmarketing surveillance study with MOBEC® 15 mg tablets
Investigator:	[redacted]
Study centres:	1,100 primarily internal and general medical practices in all federal states of Germany
Puplication (reference):	N/A
Clinical phase:	IV/PMS/ Anwendungsbeobachtung
Objectives:	The aim of the planned study is to investigate - the indication for MOBEC® in a dose of 15 mg per day - the treatments patients were receiving before switching to 15 mg MOBEC® - how treatment with 15 mg is assessed compared with previous treatment - how effective and safe treatment with 15 mg MOBEC® is considered
Methodology:	Open, non-controlled cohort study with 2 visits
No. of subjects:	
planned:	5,500:
actual:	4,760 (safety analysis set)
Diagnosis and main criteria for inclusion:	In accordance to the SPC: Osteoarthiritis, Rheumatoid Arthritis, Ankylosing Spondylitis, others, not pre-specified
Test product:	Meloxicam
dose:	15 mg
mode of admin:	oral
batch no.:	N/A
Duration of treatment:	4-8 weeks
Reference therapy:	N/A
dose:	N/A
mode of admin.:	N/A
Criteria for evaluation:	

Efficacy:	- Assessment at end of PMS - Final assessment of treatment with MOBEC® by physician (efficacy and efficacy compared with previous COX-2 inhibitor/NSAID treatment)
Safety:	Assessment of patient's present state of health - Nature and incidence of adverse reactions - Assessment on premature termination of PMS - Final assessment of treatment with MOBEC® by physician (tolerability and tolerability compared with previous COX-2 inhibitor/NSAID treatment)
Statistical methods:	descriptive statistics
SUMMARY-CONCLUSION:	
Efficacy results:	This post-marketing surveillance study was performed in 923 medical practises mainly general practices. 4760 patients participated in this study, 4446 patients (93.4%) did not discontinue the treatment with MOBEC® prematurely. 314 patients (6.6%) discontinued the treatment with MOBEC®. The reasons for this were: adverse events in 8 cases (2.5%), premature therapeutic success in 194 cases (61.8%), deterioration of the underlying disease in 42 cases (13.4%), not coming to the second appointment in 20 cases (6.4%), other reasons not related to the MOBEC® treatment in 27 cases (8.6%), no reasons were reported in 6 cases (1.9%) and discontinuation of the MOBEC® treatment in 17 cases (5.4%). The primary endpoint was the indication for a treatment with MOBEC® 15 mg tablets. 4760 patients participated in this post-marketing surveillance study. 2801 patients (56.8%) suffered from osteoarthritis. 1024 patients (21.5%) suffered from rheumatoid arthritis and 370 patients (7.8%) from ankylosing spondylitis. Other diagnoses, classified according to the ICD-10 key were mentioned for 565 patients (11.9%). The most frequent diagnoses were lumbago (58, 10.3%), nerve root disease (48, 8.5%) and back ache (38, 6.7%). The efficacy of MOBEC® was assessed as very good or good in 4308 patients (90.5%) out of 4740 patients. In 345 patients (7.2%) the efficacy was assessed as satisfactory and in 89 patients (1.9%) it was assessed as poor or very poor. For 18 patients (0.4%) there were no data regarding efficacy. Out of a total of 3380 patients pre-treated with an NSAID 2124 patients (62.8%) assessed the efficacy of MOBEC® as better than that of the pre-medication. 993 patients (29.4%) assessed the efficacy of MOBEC® as equal to that of pre-medication and 80 patients (2.4%) assessed it as poorer. For 183 patients (5.4%) there were no data regarding the comparative efficacy.
Safety results:	96.8% of the patients assessed the tolerance of MOBEC® as very good or good. 81.2% of the patients assessed the tolerance of MOBEC® as better compared with a previous NSAID treatment.

	ADR were reported in 8 cases. In 6 out of 8 patients the symptoms were mainly gastrointestinal. No ADR was serious.
Conclusions:	These results underline the good efficacy and tolerability of MOBEC® which had already been observed in comparable studies.