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**.

2. SYNOPSIS

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Mobic® Ampoules				
Name of active ingredient: Meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:**		**Addendum No.:**
Report date: 30 October 2005	**Number:** I	**Study period (years):** 2003-2005		

Title of study:	MELOXICAM (MOBIC®) AMPOULE POST MARKETING SURVEILLANCE STUDY
Investigator:	[redacted] MD
Study center(s):	[redacted]
Publication (reference):	
Clinical phase:	Phase IV
Objectives:	To determine the safety and efficacy of Mobic® ampoules in the initiation of treatment of painful exacerbations of osteoarthritis, rheumatoid arthritis and other similar painful inflammatory conditions.
Methodology:	Open label, non-comparative descriptive study
No. of subjects:	
planned:	3000
actual:	121
Diagnosis and main criteria for inclusion:	Painful acute exacerbations of inflammatory rheumatism (rheumatoid arthritis and ankylosing spondylitis), painful acute exacerbations of osteoarthritis and other similar conditions requiring acute treatment with an anti-inflammatory drug.
Test product:	Mobic® Ampoules (Meloxicam)
dose:	Meloxicam 15 mg IM daily up to 3 days (painful acute exacerbations of rheumatoid arthritis and ankylosing spondylitis) Meloxicam 7.5 mg IM daily up to 3 days (painful acute exacerbations of osteoarthritis or other similar inflammatory conditions)
mode of admin.:	Intramuscular (IM)
batch no.:	Not applicable

Duration of treatment: 3 days				
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Reference therapy:	Not Applicable
dose:	Not Applicable
mode of admin.:	Not Applicable
batch no.:	Not Applicable
Criteria for evaluation:	
Efficacy:	Evaluation for efficacy consists of an overall assessment of pain, where treatment with meloxicam IM will be gauged as effective, not effective or doubtful
Safety:	Evaluation for safety includes adverse event reporting
Statistical methods:	Descriptive statistics, comparison of degree of pain before and 60 minutes after giving the drug, comparison of level of pain on Day 1 with Day 2 and Day 3 of treatments.

SUMMARY - CONCLUSIONS:

Efficacy results:	51.4% - very effective 48.6% - effective
Safety results:	No reported adverse events
Conclusions:	Meloxicam (Mobic ®) Post-Marketing Surveillance has shown the tolerability and significant effectiveness of Mobic® Ampoules in the initiation of treatment of painful exacerbations of osteoarthritis, rheumatoid arthritis and other similar painful inflammatory conditions.