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		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Mobec®				
Name of active ingredient: Meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:**		**Addendum No.:**
Report date: 16 MAY 2003	**Number:** U03-1294	**Study period (years):** 10 July - 30 August 2002		

Title of study:	Effect of steady state meloxicam 15 mg/day on low dose aspirin (100 mg/day) induced inhibition of platelet aggregation and thromboxane synthesis in healthy males and females. An open, randomised, two-way crossover study.
Investigator:	[redacted]
Study center:	Human Pharmacology Centre, Boehringer Ingelheim Pharma GmbH & Co.KG, Biberach
Publication (reference):	No
Clinical phase:	I
Objectives:	Influence of steady state meloxicam on low dose aspirin induced inhibition of platelet aggregation and thromboxane synthesis.
Methodology:	Randomised, open label, two-way crossover
No. of subjects entered:	
total:	16 subjects, 8 males and 8 females
each treatment:	16
Diagnosis and main criteria for inclusion:	Healthy male and female subjects , age ≥ 18 and ≤ 60 years, BMI ≥ 18.5 and ≤ 29.9 kg/m^2
Test product:	Mobec® 15 mg tablet
dose:	15 mg/day
mode of admin.:	per os (p.o.)
batch no.:	202014
Duration of treatment:	Treatment 1 (meloxicam, aspirin): ten days; treatment 2 (aspirin): two days
Reference therapy:	Aspirin® 100 mg tablet
dose:	100 mg/day
mode of admin.:	p.o.
batch no.:	EATBL00
Criteria for evaluation:	Platelet aggregation to arachidonic acid, collagen and adenosine diphosphate (ADP). Serum thromboxane B_2 levels.

ARCHIVED
U03-1294

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Mobec®		**SUPPLEMENTARY SHEET**		
Name of active ingredient: Meloxicam		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:**		**Addendum No.:**
Report date: 16 MAY 2003	**Number:** U03-1294	**Study period (years):** 10 July - 30 August 2002		

Efficacy:	Efficacy was evaluated as the influence of meloxicam on aspirin-induced inhibition of platelet function. Platelet function was measured as platelet aggregation and thromboxane B_2 production.
Safety:	Adverse events, vital functions, electrocardiogram (ECG), laboratory tests, global tolerability
Statistical methods:	An ANOVA model including effects for "sequence", "subjects nested within sequences", "period" and "treatment". was fit to the pharmacodynamic data. The ratio of the expected means for 'Test/Reference' was estimated by the ratio of the corresponding Least Square Means (point estimates) and two-sided 90% confidence intervals according to Fieller's method were computed. Descriptive statistics for all other parameters was calculated.

SUMMARY – CONCLUSIONS:

Efficacy results:	Meloxicam had no effect on aspirin-induced inhibition of platelet aggregation with either arachidonic acid, collagen or ADP stimuli at all time points over the 24 hour period. Platelet aggregation with each stimulus was similar in the meloxicam-aspirin group as compared to aspirin alone. Serum thromboxane B_2 levels also did not differ between the two groups.
Safety results:	Both treatment 1 (meloxicam 15 mg/day on days 1-10 and in addition, aspirin 100 mg/day on days 5-10) and treatment 2 (aspirin 100 mg/day on days 1 and 2) were safe and well tolerated. There was only one mild and transient adverse event (dry mouth) reported. This adverse event was regarded as not drug-related. There were no relevant changes in vital signs, ECG and laboratory analyses.
Conclusions:	Meloxicam does not block the cardioprotective effects of aspirin when measured as platelet aggregation or serum TxB_2 levels. Both drugs were well tolerated irrespective of whether the combination was given or whether the drugs were administered alone.