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		**Tabulated Trial Report**	Boehringer Ingelheim
Name of finished product: MOVALIS®		**EudraCT No.:** Not applicable	**Synopsis No.: 1**
Name of active ingredient: Meloxicam		**Page:** 1of 3	
Module:		**Volume:**	
Report date:	**Trial No. / U No.:** 107.273 / UXX-XXXX	**Date of trial:** 01 March 2007 – 03 May 2008	**Date of revision** (if applicable)**:**

Title of trial:	**Assessing the impact of MOVALIS® on Health Related Quality of Life**
Principal/Coordinating Investigator:	Not applicable
Trial sites:	Multicenter study in Czech Republic, Russia, Estonia, Slovakia and Croatia
Publication (reference):	NA
Clinical phase:	IV (Post-marketing surveillance study)
Objectives:	The objective of the observational study was to examine the effect of MOVALIS® therapy on health related quality of life (HRQoL) in patients with painful osteoarthritis or rheumatoid arthritis in the diverse region of Central and Eastern Europe. The SF-12v2 (Medical Outcomes Study, Short Form 12, version 2) was used as the instrument to measure any change in physical wellbeing (physical component summary, PCS) and mental wellbeing (mental component summary, MCS) of patients following MOVALIS® therapy.
Methodology:	Post-marketing observational study
No. of subjects:	
planned:	entered: 4150
actual:	enrolled: 3569 Treatment MOVALIS® 7.5 – 15mg once daily entered: 3569 treated: 3473 analysed (for primary endpoint)
Diagnosis and main criteria for inclusion:	• Patients with symptoms of acute, painful osteoarthritis or rheumatoid arthritis • Patients requiring therapy with non-steroidal anti-inflammatory drugs (NSAIDs)

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Test product:	MOVALIS®
dose:	7.5 – 15mg once daily, depending on clinical need and judgement of physician
mode of admin.:	intramuscular injection and/or tablet
batch no.:	Not applicable
Reference therapy:	Not applicable as no comparator was used
dose:	
mode of admin.:	
batch no.:	
Duration of treatment:	Approximately four weeks. Since this was an observational study, duration of treatment was based on individual patient need and physician judgement. Physicians were advised that as for all non-steroidal anti-inflammatory drugs, it is recommended to prescribe MOVALIS® at the lowest effective dose for the shortest possible duration to control symptoms.
Criteria for evaluation:	Impact of MOVALIS® therapy on Health realted Quality of life in patients with symptoms of acute, painful osteoarthritis or rheumatoid arthritis.
Efficacy / clinical pharmacology:	The SF-12v2 was used to measure any change in physical wellbeing (PCS) and mental wellbeing (MCS) of patients following MOVALIS® therapy. Patient and physician assessment of general efficacy of MOVALIS® was examined using a five point scale Patient assessment of pain intensity was assessed with a 100 mm Visual Analogue Scale (VAS)
Safety:	Serious and non serious adverse events were recorded
Statistical methods:	The focus of analysis was the change from baseline in the SF-12v2 health survey scores (PCS and MCS) after four weeks. Of further interest was the change in patient assessment of pain intensity on VAS after 4 weeks. The patient and physician assessments of general efficacy of MOVALIS® were measured on a five-point verbal rating scale scale.

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SUMMARY – CONCLUSIONS:

Efficacy / clinical pharmacology results:

There was a significant increase in PCS score from baseline to visit 2 for the total study population (11.2 points, from 32.3 to 43.5 ($p< 0.0001$) indicating an improvement in physical wellbeing following MOVALIS® therapy. There was a significant increase in MCS score from baseline to visit 2 for the total study population (6.2 points, from 40.06 to 46.2 ($p< 0.0001$) indicating an improvement in mental wellbeing following MOVALIS® therapy.

The level of pain intensity, measured by VAS, following MOVALIS® therapy decreased significantly (from 66.9 to 25.0 (SD ± 15.53 ($P<0.0001$)) in the total study population.

94% of patients and 96% of physicians rated the efficacy of MOVALIS® at least as „good".

Safety results:

A total of 68 (2%) of patients reported a total of 132 adverse events (AEs) during the study. 37% of total AEs were gastrointestinal disorders, with nausea as the most symptom type. The type of reported AEs were in line with previous studies of MOVALIS® and are recognised side effects of Meloxicam. The reporting of AEs was generally lower in this observational study than in controlled trials of MOVALIS®. No serious AEs or deaths were reported in the study.

Conclusions:

This prospective, open-label, multicentre, non-interventional study demonstrated that both physical and mental wellbeing aspects of health related quality of life, as measured by SF12v2 scores, improved significantly in patients with painful osteoarthritis or rheumatoid arthritis after approximately 4 weeks of MOVALIS® treatment.

Pain intensity, measured by visual analogue scale, decreased significantly following MOVALIS® therapy and both physicians and patients rated the efficacy of MOVALIS® highly. Few adverse events, were reported in the study and there we no unexpected or serious adverse events.