LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Public Assessment Report

# Scientific discussion

# Melox
# (meloxicam)

# SE/H/1297/01/DC

**This module reflects the scientific discussion for the approval of Melox. The procedure was finalised at 2014-01-15. For information on changes after this date please refer to the module 'Update'.**

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# I. INTRODUCTION

The application for Melox, 10 mg/ml, solution for injection, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Medochemie Ltd. applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and BG, CY, EE, LV, MT and RO as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Mobic, 15mg/1,5ml, solution for injection, authorised in FR since 2000, with Boehringer Ingelheim France as marketing authorisation holder.

The concept of a European reference product is used for BG and MT. The full composition of this reference product authorised in FR has been provided by the RMS.

For approved indications, see the Summary of Product Characteristics.

# II. QUALITY ASPECTS

## II.1 Introduction

Melox is presented in the form of a solution for injection containing 10 mg of meloxicam per ml. The excipients are meglumine, glycofurol, poloxamer 188, sodium chloride, glycine, sodium hydroxide and water for injections. The drug product is supplied in clear glass ampoules. Each ampoule contains 1.65 ml of solution (overfill of 0.15 ml).

## II.2 Drug Substance

The drug substance meloxicam is described in monograph no. 2373 published in the European Pharmacopeia (Ph. Eur.).

Meloxicam is a pale yellow powder, practically insoluble in water. The solubility in aqueous solutions increases with the increase of pH.

The structure of meloxicam has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification complies with the requirements of the Ph. Eur. The analytical methods applied are suitably described and validated.

Stability studies have been conducted and the data provided are sufficient to confirm the re-test period.

## II.3 Medicinal Product

The drug product is a clear and yellow solution for injection.

Sufficient information has been provided regarding the pharmaceutical development work. The formulation is essentially similar to that of the reference medicinal product Mobic 15mg/1.5ml

solution for injection. No materials of animal or human origin are used in the manufacture of the drug product.

The manufacturing process has been sufficiently described and critical steps identified. Results from the process validation studies confirm that the process is under control and ensure both batch to batch reproducibility and compliance with the product specification. It has been verified that the product is manufactured in accordance with the principles of Good Manufacturing Practise.

The release and shelf-life specifications are considered appropriate to control the quality of the finished product in relation to its intended purpose. The general requirements of the Ph. Eur. monograph “Parenteral preparations” are fulfilled and the limits regarding related substances are in line with the ICH recommendations.

Stability studies under ICH conditions have been performed and the data presented support the shelf-life claimed in the SPC.

# III. NON-CLINICAL ASPECTS

## III.1 Discussion on the non-clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to preclinical data, no further such data have been submitted or are considered necessary.

# IV. CLINICAL ASPECTS

## IV.1 Pharmacokinetics

The applicant has not submitted any bioequivalence studies. Absence of bioequivalence studies is acceptable since the applied product is to be administered as an intramuscular solution containing the same active substance in the same concentration and the same excipients as the currently authorised product.

## IV.2 Discussion on the clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

# V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User consultation
The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PL was Czech.

The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

The risk/benefit ratio is considered positive and Melox, 10 mg/ml, solution for injection, is recommended for approval.

# VI. APPROVAL

The Decentralised procedure for Melox, 10 mg/ml, solution for injection, was successfully finalised on 2014-01-15.

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# Public Assessment Report – Update

| Scope | Procedure number | Product Information affected | Date of start of the procedure | Date of end of procedure | Approval/ non approval | Assessment report attached |
|---|---|---|---|---|---|---|
| | | | | | | Y/N (version) |

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