LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Melox
# (meloxicam)

# SE/H/1297/01/DC

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# Summary Public Assessment Report

Melox

(meloxicam)

10 mg/ml, solution for injection

This is a summary of the public assessment report (PAR) for Melox. It explains how Melox was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Melox.

For practical information about using Melox, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Melox and what is it used for?

Melox is a ‘generic medicine’. This means that Melox is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Mobic.

Melox is used in adults for short-term treatment of the inflammatory rheumatic diseases rheumatoid arthritis and ankylosing spondylitis (Bechterew's disease) when administration by mouth or rectally is not possible.

## How does Melox work?

Melox contains an active substance called meloxicam. Meloxicam belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), which are used to reduce inflammation**,** fever and pain.

## How is Melox used?

The pharmaceutical form of Melox is solution for injection for intramuscular route.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

## What benefits of Melox have been shown in studies?

No additional studies were needed as Melox is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Mobic.

## What are the possible side effects of Melox?

Because Melox is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

**Why is Melox approved?**

It was concluded that, in accordance with EU requirements, Melox has been shown to have comparable quality and to be similar to the reference medicine Mobic. Therefore, the Medical Products Agency in Sweden decided that, as for Mobic, the benefits are greater than its risks and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of Melox?**

A risk management plan has been developed to ensure that Melox is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Melox, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

**Other information about Melox**

The marketing authorisation for Melox was granted on 2014-01-30 in Sweden.

The full PAR for Melox can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Melox, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2014-01.