

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl 5 mg/ml solution for injection for dogs and cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Meloxicam 5 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Ethanol anhydrous	150 mg
Poloxamer 188	
Macrogol 300	
Glycine	
Sodium citrate	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid (for pH adjustment)	
Meglumine	
Water for injections	

Clear, yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs and cats.

### 3.2 Indications for use for each target species

#### Dogs:

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

#### Cats:

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

### 3.3 Contraindications

Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals less than 6 weeks of age nor in cats of less than 2 kg.

### 3.4 Special warnings

For post-operative pain relief in cats, safety has only been documented after thiopental/halothane anaesthesia.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Any oral follow-up therapy using meloxicam or other Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental self-injection may give rise to pain.

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

#### Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Dogs and cats:

Very rare ( $<1$ animal / 10,000 animals treated, including isolated reports):	Vomiting <sup>1</sup> , diarrhoea <sup>1</sup> , blood in faeces <sup>1,2</sup> , <sup>1</sup> , gastric ulcer <sup>1</sup> , small intestine ulcer <sup>1</sup> Appetite loss <sup>1</sup> , lethargy <sup>1</sup> Renal failure <sup>1</sup> Anaphylactoid reaction <sup>1</sup>
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<sup>1</sup> In dogs, these adverse events occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

<sup>2</sup>Occult

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating animals.

### 3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects.

Meloxidyl must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Concurrent administration of potential nephrotoxic drugs should be avoided.

In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

### **3.9 Administration routes and dosage**

#### **Dogs:**

##### *Musculo-skeletal disorders:*

Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).

Meloxidyl 1.5 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

##### *Reduction of post-operative pain (over a period of 24 hours):*

Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

#### **Cats:**

Reduction of post-operative pain:

Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.

Particular care should be taken with regard to the accuracy of dosing. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

In the case of overdose, symptomatic treatment should be initiated.

### **3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

Not applicable.

### **3.12 Withdrawal periods**

Not applicable.

## **4. PHARMACOLOGICAL INFORMATION**

### **4.1 ATCvet code: QM01AC06**

### **4.2 Pharmacodynamics**

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class, which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it

also inhibits collagen-induced thrombocyte aggregation. In vitro and in vivo studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

### **4.3 Pharmacokinetics**

#### Absorption

Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 mcg/ml in dogs and 1.1 mcg/ml in cats were reached approximately 2.5 hours and 1.5 hours post administration, respectively.

#### Distribution

There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

#### Metabolism

In dogs, meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

#### Elimination

Meloxicam is eliminated with a half-life of 24 hours in dogs and 15 hours in cats. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 Major incompatibilities**

None known.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

### **5.3 Special precautions for storage**

Do not store above 25 °C.

### **5.4 Nature and composition of immediate packaging**

Colourless type I glass injection vial of 10 ml, closed with a grey EPDM (Ethylene Propylene Diene Monomer) or flurotec rubber stopper and sealed with a flip off aluminium violet seal in a cardboard box.

### **5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale

**7. MARKETING AUTHORISATION NUMBER(S)**

EU/2/06/070/004

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 15/01/2007

**10 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

{MM/YYYY}

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).