

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl 0.5 mg/ml oral suspension for cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of Meloxidyl 0.5 mg/ml oral suspension for cats contains:

### Active substance:

Meloxicam 0.5 mg

### Excipient:

Sodium benzoate (E 211) 2.0 mg

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Oral suspension.

Pale yellow suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cats.

### 4.2 Indications for use, specifying the target species

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.

Alleviation of pain and inflammation in chronic musculo-skeletal disorders in cats.

### 4.3 Contraindications

- Do not use in pregnant or lactating animals.
- Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
- Do not use in case of hypersensitivity to the active substance or to any of the excipients.
- Do not use in cats less than 6 weeks of age.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

#### Special precautions for use in animals

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

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

#### Post-operative pain and inflammation following surgical procedures:

In case additional pain relief is required, multimodal pain therapy should be considered.

#### Chronic musculoskeletal disorders:

Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

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

People with known hypersensitivity to Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

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

### **4.6 Adverse reactions (frequency and seriousness)**

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. These side effects are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

### **4.7 Use during pregnancy, lactation or lay**

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (See section 4.3).

### **4.8 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.

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 pharmacological properties of the products used previously.

### **4.9 Amounts to be administered and administration route**

#### **Dosage**

#### Post-operative pain and inflammation following surgical procedures:

After initial treatment with meloxicam 2 mg/ml solution for injection for cats, continue treatment 24 hours later with Meloxidyl 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg bodyweight. The oral follow-up dose may be administered once daily (at 24 hour intervals) for up to four days.

#### Chronic musculo-skeletal disorders:

Initial treatment is a single oral dose of 0.1 mg meloxicam/kg body weight on the first day.

Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg body weight.

Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded.

A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

#### **Route and method of administration**

Shake well before use. To be administered orally either mixed with food or directly into the mouth. The suspension can be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale (from 1 kg to 10 kg) which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

Avoid introduction of contamination during use.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.

In case of overdose, adverse reactions, as listed in Section 4.6, are expected to be more severe and more frequent. In the case of overdose symptomatic treatment should be initiated.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams)  
ATC-vet code: QM01AC06

#### **5.1 Pharmacodynamic properties**

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).

#### **5.2 Pharmacokinetic particulars**

##### Absorption

If the animal is fasted when dosed, the maximal plasma concentrations are obtained after approximately 3 hours. If the animal is fed at the time of dosing, the absorption may be slightly delayed.

##### Distribution

There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97 % of meloxicam is bound to plasma proteins.

##### Metabolism

Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Five major metabolites have been identified. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. As for

other species investigated, the main pathway of meloxicam biotransformation in cat is oxidation and there are no pharmacologically active metabolites.

### Elimination

Meloxicam is eliminated with a half-life of 24 hours. The detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21% of the recovered dose is eliminated in urine (2% as unchanged meloxicam, 19% as metabolites) and 79% in the faeces (49% as unchanged meloxicam, 30% as metabolites).

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

- Xanthan gum
- Silica colloidal anhydrous
- Sorbitol liquid non-crystallising
- Glycerol
- Xylitol
- Sodium benzoate (E 211)
- Citric acid anhydrous
- Purified water

### **6.2 Major incompatibilities**

None known.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 30 months  
Shelf life after first opening the immediate packaging: 6 months

### **6.4. Special precautions for storage**

This veterinary medicinal product does not require any special storage conditions.

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

#### Material of the primary container

High density polyethylene bottle with high density polyethylene tamper evidence screw cap.  
Type III glass bottle with high density polyethylene tamper evidence screw cap.  
Low density polyethylene syringe insert for the polypropylene measuring syringe.

#### Pack sizes

Cardboard box containing 15 ml high density polyethylene bottle with one measuring syringe.  
Cardboard box containing 5 ml glass bottle with one measuring syringe.  
The measuring syringe has a kg-body weight scale for cats (1 to 10 kg).  
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale  
10 av. de La Ballastière  
33500 Libourne  
France

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

EU/2/06/070/008  
EU/2/06/070/010

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 15.01.2007  
Date of last renewal: 19.12.2011

**10. DATE OF REVISION OF THE TEXT**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.