

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 1.5 mg/ml oral suspension for dogs

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Composition for 1 ml

### **Active substance (s)**

Meloxicam                      1.5 mg

### **Excipients**

Sodium benzoate              2 mg

For the full list of excipients, see section 6.1

## **3. PHARMACEUTICAL FORM**

Pale yellow suspension.

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Dogs.

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

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

### **4.3 Contraindications**

Do not use in pregnant or lactating animals.

Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of individual hypersensitivity to the product.

Do not use in dogs 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 side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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

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

People with known hypersensitivity to 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 drug reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy have occasionally been reported. These side effects 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.

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

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.

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

Oral use.

Shake well before use.

To be administered mixed with food.

Initial treatment is a single dose of 0.2 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 0.1 mg meloxicam/kg body weight.

Particular care should be taken with regard to the accuracy of dosing.

The suspension can be given using the measuring syringes provided in the package. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight). Thus, for the first day, twice the maintenance volume will be required.

The suspension could be administered using the smallest syringe for dogs less than 7 kg body weight (one graduation corresponding to 0.5 kg of body weight) or the largest syringe for dogs over than 7 kg body weight (one graduation corresponding to 2.5 kg of body weight).

A clinical response is normally seen within 3 – 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Avoid introduction of contamination during use.

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

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

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

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non steroids.  
ATC-vet: 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

Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 7.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

##### 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. The volume of distribution is 0.3 l/kg.

##### Metabolism

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. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Xanthan gum  
Silica colloidal anhydrous  
Sorbitol liquid non-crystallising  
Glycerol, xylitol  
Sodium benzoate  
Citric acid anhydrous  
Purified water.

### **6.2 Major incompatibilities**

Not applicable.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.  
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.  
Low density polyethylene syringe insert for the polypropylene measuring syringes.

#### Pack sizes

Two measuring syringes are provided per each presentation.

10 ml bottle in a cardboard box  
32 ml bottle in a cardboard box  
100 ml bottle in a cardboard box

Not all pack sizes may be marketed.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products 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 avenue de la Ballastière  
33500 Libourne  
France

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

EU/2/06/070/001

EU/2/06/070/002

EU/2/06/070/003

**9. DATE OF THE 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.

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

### **Active substance:**

Meloxicam 5 mg.

### **Excipients:**

Ethanol anhydrous 150 mg

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Solution for injection.

Clear, yellow solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs and cats.

### 4.2 Indications for use, specifying the 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.

### 4.3 Contraindications

- Do not use in pregnant or lactating animals.
- 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 case 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.

### 4.4 Special warnings for each target species

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

## **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 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 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.

## **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.

In dogs, these side effects 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.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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 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.

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.



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

##### **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.

Avoid introduction of contamination during use.

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

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

Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 µg/ml in dogs and 1.1 µg/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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Ethanol anhydrous  
Poloxamer 188  
Glycofurol  
Meglumine  
Glycine  
Sodium chloride  
Sodium hydroxide  
Water for injection

### **6.2 Major incompatibilities**

None known.

### **6.3 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.

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

Do not store above 25°C.

### **6.5 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.

### **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 avenue de la Ballastière  
33500 Libourne  
France

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

EU/2/06/070/004

**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.

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl 20 mg/ml solution for injection for cattle, pigs and horses

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of Meloxidyl 20 mg/ml solution for injection contains:

### **Active substance:**

Meloxicam 20 mg

### **Excipient:**

Ethanol anhydrous 150 mg

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Solution for injection

Clear, colourless to yellowish solution.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cattle, pigs and horses

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

#### **Cattle:**

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.

For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.

For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

For the relief of post-operative pain following dehorning in calves.

#### **Pigs:**

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.

For adjunctive therapy in the treatment of puerperal septicaemia and toxæmia (mastitis–metritis–agalactia syndrome) with appropriate antibiotic therapy.

#### **Horses:**

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.

For the relief of pain associated with equine colic.

### 4.3 Contraindications

See also section 4.7.

Do not use in horses less than 6 weeks of age.

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.  
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

#### **4.4 Special warnings for each target species**

Treatment of calves with Meloxidyl 20 minutes before dehorning reduces post-operative pain.  
Meloxidyl alone will not provide adequate pain relief during dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

#### **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 very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

##### 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.

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

In cattle and pigs, subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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**

##### **Cattle and pigs:**

Can be used during pregnancy and lactation.

##### **Horses:**

Do not use in pregnant or lactating mares.

Do not use in horses producing milk for human consumption.

See also section 4.3.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

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

##### **Cattle:**

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

##### **Pigs:**

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

##### **Horses:**

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

Avoid introduction of contamination during use.

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

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

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

##### **Cattle:**

Meat and offal: 15 days

Milk: 5 days

##### **Pigs:**

Meat and offal: 5 days

##### **Horses:**

Meat and offal: 5 days.

### **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, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B<sub>2</sub> induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

## **5.2 Pharmacokinetic particulars**

### Absorption

After a single subcutaneous dose of 0.5 mg meloxicam/kg, C<sub>max</sub> values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.

After two intramuscular doses of 0.4 mg meloxicam/kg, a C<sub>max</sub> value of 1.9 µg/ml was reached after 1 hour in pigs.

### Distribution

More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

### Metabolism

Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain 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. The metabolism in horses has not been investigated.

### Elimination

Meloxicam is eliminated with a half-life of 26 hours and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively.

In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.

In horses, after intravenous injection meloxicam is eliminated with a terminal half-life of 8.5 hours.

Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Ethanol, anhydrous  
Poloxamer 188  
Macrogol 300  
Glycine  
Sodium citrate  
Sodium hydroxide (for pH adjustment)  
Hydrochloric acid (for pH adjustment)  
Meglumine  
Water for injections

### **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: 28 days.

#### **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**

Cardboard box containing 1 colourless glass vial of 50 ml, 100 ml or 250 ml.  
Each vial is closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

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 avenue de la Ballastière  
33500 Libourne  
France

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

EU/2/06/070/005  
EU/2/06/070/006  
EU/2/06/070/007

### **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.



## 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.

## **ANNEX II**

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**
- D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer of the biological active substances

Not applicable.

Name and address of the manufacturers responsible for batch release

**Meloxidyl 1.5 mg/ml**

Ceva Santé Animale - Z.I. Très le Bois - 22600 Loudéac - France

Vetem SpA - Lungomare Pirandello, 8 - 92014 Porto Empedocle (AG) - Italy

**Meloxidyl 5 mg/ml**

Ceva Santé Animale – 10 avenue de la Ballastière – 33500 Libourne - France

**Meloxidyl 20 mg/ml**

Ceva Santé Animale – 10 avenue de la Ballastière – 33500 Libourne - France

**Meloxidyl 0.5 mg/ml**

Ceva Santé Animale - Z.I Très le Bois - 22600 Loudéac – France

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.

**C. STATEMENT OF THE MRLs**

Meloxidyl 1.5 mg/ml - Meloxidyl 5 mg/ml - Meloxidyl 0.5 mg/ml

Not applicable

### Meloxidyl 20 mg/ml:

The active substance in Meloxidyl is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

<b>Pharmacologically active substance(s)</b>	<b>Marker residue</b>	<b>Animal species</b>	<b>MRLs</b>	<b>Target tissues</b>	<b>Other provisions</b>
Meloxicam	Meloxicam	Bovine	20 µg/kg 65 µg/kg 65 µg/kg 15 µg/kg	Muscle Liver Kidney Milk	
		Porcine	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	
		Equidae	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

#### **D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

Ceva Santé Animale ensures that the system of pharmacovigilance, as described in Part I of the marketing authorisation application, is in place and functioning before and whilst the veterinary medicinal product is on the market.



**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box of 10 ml vial  
Cardboard box of 32 ml vial  
Cardboard box of 100 ml vial

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 1.5 mg/ml oral suspension for dogs.  
Meloxicam

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains 1.5 mg of meloxicam

**3. PHARMACEUTICAL FORM**

Oral suspension.

**4. PACKAGE SIZE**

10 ml  
32 ml  
100 ml

**5. TARGET SPECIES**

Dogs.

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Shake well before use.  
Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP:

Once opened use within 6 months.

**11. SPECIAL STORAGE CONDITIONS**

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary subscription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale  
10 avenue de la Ballastière  
33500 Libourne  
France

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

EU/2/06/070/001

EU/2/06/070/002

EU/2/06/070/003

**17. MANUFACTURER'S BATCH NUMBER**

Lot:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

Label of 10 ml vial  
Label of 32 ml vial  
Label of 100 ml vial

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 1.5 mg/ml oral suspension for dogs.  
Meloxicam

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**3. CONTENTS BY WEIGHT, BY VOLUME OR NUMBER OF DOSES**

10 ml  
32 ml  
100 ml

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot:

**7. EXPIRY DATE**

EXP:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box of 10 ml vial**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 5 mg/ml solution for injection for dogs, cats  
Meloxicam

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains 5 mg of meloxicam.

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

10 ml

**5. TARGET SPECIES**

Dogs and cats

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Dogs: intravenous or subcutaneous use  
Cats: subcutaneous use

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

Do not use in pregnant or lactating animals.  
Read the package leaflet before use.

**10. EXPIRY DATE**

EXP

Once broached, use within 28 days.

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25° C.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Read the package leaflet before use.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale  
10 avenue de la Ballastière  
33500 Libourne  
France

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

EU/2/06/070/004

**17. MANUFACTURER’S BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Label of 10 ml vial**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 5 mg/ml solution for injection for dogs, cats  
Meloxicam

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

1 ml contains 5 mg of meloxicam.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

10 ml

**4. ROUTE(S) OF ADMINISTRATION**

Dogs: IV or SC  
Cats: SC

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP  
Once broached, use within 28 days.

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box of 50 ml vial  
Cardboard box of 100 ml vial  
Cardboard box of 250 ml vial

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 20 mg/ml solution for injection for cattle, pigs, horses  
Meloxicam

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains 20 mg of meloxicam.

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

50 ml  
100 ml  
250 ml

**5. TARGET SPECIES**

Cattle, pigs, horses

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Cattle: Subcutaneous or Intravenous use  
Pigs: Intramuscular use  
Horses: Intravenous use

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

**Withdrawal periods:**

Cattle: Meat and offal: 15 days; Milk: 5 days

Pigs: Meat and offal: 5 days

Horses: Meat and offal: 5 days.

**9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP

Once broached, use within 28 days.

**11. SPECIAL STORAGE CONDITIONS**

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale  
10 avenue de la Ballastière  
33500 Libourne  
France

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

EU/2/06/070/005

EU/2/06/070/006

EU/2/06/070/007

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Label of 100 ml vial**

**Label of 250 ml vial**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 20 mg/ml solution for injection for cattle, pigs, horses  
Meloxicam

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains 20 mg of meloxicam.

**3. PHARMACEUTICAL FORM**

Solution for injection

**4. PACKAGE SIZE**

100 ml

250 ml

**5. TARGET SPECIES**

Cattle, pigs, horses

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Cattle: Subcutaneous or Intravenous use

Pigs: Intramuscular use

Horses: Intravenous use

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

**Withdrawal periods:**

Cattle: Meat and offal: 15 days; Milk: 5 days

Pigs: Meat and offal: 5 days

Horses: Meat and offal: 5 days.

**9. SPECIAL WARNING(S), IF NECESSARY**

**10. EXPIRY DATE**

EXP

Once broached, use within 28 days.

**11. SPECIAL STORAGE CONDITIONS**

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Ceva Santé Animale  
10 avenue de la Ballastière  
33500 Libourne  
France

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

EU/2/06/070/006  
EU/2/06/070/007

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Label of 50 ml vial**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 20 mg/ml solution for injection for cattle, pigs, horses  
Meloxicam

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

1 ml contains 20 mg of meloxicam.

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

50 ml

**4. ROUTE(S) OF ADMINISTRATION**

Cattle: SC or IV  
Pigs: IM  
Horses: IV

**5. WITHDRAWAL PERIOD(S)**

**Withdrawal periods:**

Cattle: Meat and offal: 15 days; Milk: 5 days

Pigs: Meat and offal: 5 days

Horses: Meat and offal: 5 days.

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

Once broached, use within 28 days.

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box of 15 ml vial

Cardboard box of 5 ml vial

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 0.5 mg/ml oral suspension for cats

Meloxicam

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains 0.5 mg of meloxicam.

**3. PHARMACEUTICAL FORM**

Oral suspension.

**4. PACKAGE SIZE**

15 ml

5 ml

**5. TARGET SPECIES**

Cats

**6. INDICATION(S)**

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Shake well before use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP

Once opened, use within 6 months.

**11. SPECIAL STORAGE CONDITIONS**

**12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

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

EU/2/06/070/008

EU/2/06/070/010

**17. MANUFACTURER’S BATCH NUMBER**

Lot



**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Label of 15 ml vial**

**Label of 5 ml vial**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 0.5 mg/ml oral suspension for cats

Meloxicam

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

15 ml

5 ml

**4. ROUTE(S) OF ADMINISTRATION**

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Meloxidyl 1.5 mg/ml oral suspension for dogs**  
**10, 32 & 100 ml**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

Ceva Santé Animale  
10 avenue de la Ballastière  
33500 Libourne  
France

Manufacturers responsible for batch release:

Ceva Santé Animale  
Z.I. Très le Bois  
22600 Loudéac  
France

Vetem SpA  
Lungomare Pirandello, 8  
92014 Porto Empedocle (AG)  
Italy

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 1.5 mg/ml oral suspension for dogs.  
Meloxicam

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS**

Each ml contains:

- 1.5 mg of meloxicam
- 2 mg of sodium benzoate

**4. INDICATION(S)**

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

**5. CONTRAINDICATIONS**

Do not use in pregnant or lactating animals.

Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of individual hypersensitivity to the product.

Do not use in dogs less than 6 weeks of age.

## 6. ADVERSE REACTIONS

Typical adverse drug reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy have occasionally been reported. These side effects 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.

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)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon

## 7. TARGET SPECIES

Dogs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

Shake well before use. To be administered mixed with food.

Initial treatment is a single dose of 0.2 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 0.1 mg meloxicam/kg body weight.

The suspension can be given using the measuring syringes provided in the package. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1mg Meloxicam/kg body weight). Thus, for the first day, twice the maintenance volume will be required.

Dosing procedure using the measuring syringe:



Shake bottle well.  
Push down and  
unscrew bottle top.

Attach the dosing  
syringe to the  
bottle by gently  
pushing the end  
onto the top of the  
bottle.

Turn the bottle and  
syringe upside  
down. Withdraw  
the plunger until  
the black line on  
the plunger  
corresponds to  
your dog's  
bodyweight in  
kilograms.

Return the bottle  
and syringe  
upright and  
remove the  
syringe.

Depress the  
plunger to empty  
the contents of the  
syringe onto the  
food.

A clinical response is normally seen within 3-4 days. Treatment should be discontinued after 10 days after the latest if no clinical improvement is apparent.

To avoid introduction of external contaminants during use, do not remove the bottle insert and keep the provided syringes only for this product.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Particular care should be taken with regard to the accuracy of dosing.

The suspension could be administered using the smallest syringe for dogs less than 7 kg body weight (one graduation corresponding to 0.5 kg of body weight) or the largest syringe for dogs over than 7 kg body weight (one graduation corresponding to 2.5 kg of body weight).

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Shelf life after first opening the container: 6 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month.

## **12. SPECIAL WARNING(S)**

- If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought.
- Avoid use in any dehydrated, hypovolaemic or hypotensive animal, if there is a potential risk of increased renal toxicity.
- 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.
- 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.
- People with known hypersensitivity to 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.
- In the case of overdose, seek medical advice.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

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

**15. OTHER INFORMATION**

10, 32 or 100 ml bottle with two syringes per presentation.

Not all pack sizes may be marketed.

**PACKAGE LEAFLET:**  
**Meloxidyl 5 mg/ml solution for injection for dogs, cats**  
**10 ml**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:  
Ceva Santé Animale –10 avenue de la Ballastière – 33500 Libourne - France

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 5 mg/ml solution for injection for dogs, cats  
Meloxicam

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Meloxicam 5 mg/ml  
Excipients: Ethanol 150 mg/ml

Clear, yellow solution.

**4. INDICATION(S)**

**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.

**5. CONTRAINDICATIONS**

Do not use in pregnant or lactating animals.

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 case 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.

**6. ADVERSE REACTIONS**

Typical adverse reactions of Non Steroidal Anti-Inflammatory Drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported. In dogs, these side effects 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.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon

## **7. TARGET SPECIES**

Dogs and cats.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

### **Dosage for each species**

Dogs: single administration of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg).

Cats: single administration of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg).

### **Method and route of administration**

#### Dogs:

Musculo-skeletal disorders: single subcutaneous injection.

Meloxidyl 1.5 mg/ml oral suspension for dogs 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 before surgery, for example at the time of induction of anaesthesia.

#### Cats:

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery: single subcutaneous injection before surgery, for example at the time of induction of anaesthesia.

Avoid introduction of contamination during use.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Particular care should be taken with regard to the accuracy of dosing.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the cardboard box and the vial after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.



## **12. SPECIAL WARNING(S)**

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

### 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 increased renal toxicity.

Any oral follow-up therapy using meloxicam or other 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 NSAIDs should avoid contact with the veterinary medicinal product.

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

### Pregnancy and lactation:

See section "Contraindications"

### 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<sup>®</sup> 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.

### Overdose (symptoms, emergency procedures, antidotes):

In the case of overdose symptomatic treatment should be initiated.

### Incompatibilities

None known.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

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

**15. OTHER INFORMATION**

Pack size:

Cardboard box containing one 10 ml vial.

**PACKAGE LEAFLET:**  
**Meloxidyl 20 mg/ml solution for injection for cattle, pigs, horses**  
**50, 100, & 250 ml**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:  
Ceva Santé Animale –10 avenue de la Ballastière – 33500 Libourne - France

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 20 mg/ml solution for injection for cattle, pigs, horses  
Meloxicam

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

Meloxicam 20 mg/ml  
Excipients: Ethanol anhydrous 150 mg/ml  
Clear, colourless to yellowish solution.

**4. INDICATION(S)**

**Cattle:**

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.

For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.

For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

For the relief of post-operative pain following dehorning in calves.

**Pigs:**

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.

For adjunctive therapy in the treatment of puerperal septicaemia and toxemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

**Horses:**

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.

For the relief of pain associated with equine colic.

**5. CONTRAINDICATIONS**

Do not use in horses less than 6 weeks of age.

Do not use in pregnant or lactating mares.

Do not use in horses producing milk for human consumption.

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

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

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

## **6. ADVERSE REACTIONS**

In cattle and pigs, subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon .

## **7. TARGET SPECIES**

Cattle, pigs and horses

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

### **Cattle:**

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

### **Pigs:**

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

### **Horses:**

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

## **9. ADVICE ON CORRECT ADMINISTRATION**

Avoid introduction of contamination during use.

## **10. WITHDRAWAL PERIOD(S)**

Cattle: meat and offal: 15 days; milk: 5 days

Pigs: meat and offal: 5 days

Horses: meat and offal: 5 days

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the cardboard box and vial after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

## **12. SPECIAL WARNING(S)**

Treatment of calves with Meloxidyl 20 minutes before dehorning reduces post-operative pain.

Meloxidyl alone will not provide adequate pain relief during dehorning procedure. To obtain pain relief during surgery co-medication with an appropriate analgesic is needed.

### 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 very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

### 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 this package leaflet or the label to the physician.

### Pregnancy and lactation:

Cattle and pigs: Can be used during pregnancy and lactation.

Horses: See section "Contraindications".

### Interaction with other medicinal products and other forms of interactions:

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

### Overdose (symptoms, emergency procedures, antidotes):

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

### Incompatibilities

None known.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

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

**15. OTHER INFORMATION**

Cardboard box containing 1 colourless glass vial of 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.

**PACKAGE LEAFLET:**  
**Meloxidyl 0.5 mg/ml oral suspension for cats**  
**15 & 5 ml**

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Ceva Santé Animale – Z.I. Très le Bois - 22600 Loudéac - France

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Meloxidyl 0.5 mg/ml oral suspension for cats

Meloxicam

**3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

One ml contains:

Meloxicam	0.5 mg
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Sodium benzoate	2 mg
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**4. INDICATION(S)**

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.

**5. 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.

**6. ADVERSE REACTIONS**

Typical adverse reactions of non-steroidal anti-inflammatory drugs (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).  
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon

## **7. TARGET SPECIES**

Cats.

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

### **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.

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 (i.e. 0.05 mg meloxicam/kg body weight). Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

Avoid introduction of contamination during use.

## **9. ADVICE ON CORRECT ADMINISTRATION**

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

Please carefully follow the instructions of the veterinarian.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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



Do not use this veterinary medicinal product after the expiry date which is stated on the label and the cardboard box after EXP. The expiry date refers to the last day of that month.  
Shelf life after first opening the container: 6 months.

## **12. SPECIAL WARNING(S)**

### 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 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.

### Pregnancy and lactation:

See section "Contraindications".

### 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. The product 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.

### Overdose (symptoms, emergency procedures, antidotes):

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 "Adverse reactions" are expected to be more severe and more frequent. In the case of overdose symptomatic treatment should be initiated.

### Incompatibilities

None known.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

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

#### **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

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

#### **15. OTHER INFORMATION**

##### 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.