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 a 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 Contra-indications

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, including special precautions to be taken by the person administering the medicinal product to the animals

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.

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 periods for the various foodstuffs, including those for which the withdrawal period is zero

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non steroids.

ATCvet: 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

<u>Absorption</u>
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.

<u>Distribution</u>
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.

<u>Metabolism</u>
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.

<u>Elimination</u>
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 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
After first opening: 6 months.

6.4 Special precautions for storage

No special precautions for storage.

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
32 ml bottle
100 ml bottle

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, if appropriate

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 OR DATE OF 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 a 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.

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)
ATCvet 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 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) 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 a 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 toxaemia (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.

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 B2 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, Cmaxvalues 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 Cmax 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 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 a 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

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.

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)
ATCvet 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

<u>Absorption</u>
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.

<u>Distribution</u>
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 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).

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 Loudeac - 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
ACCORD HEALTHCARE LIMITED - Sage House - 319 Pinner Road – Harrow – Middlesex
HA1 4HF - United Kingdom

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:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs	Target tissues	Other provisions
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 AND OTHER SUBSTANCES

1 ml contains:
Meloxicam 1.5 mg
Sodium benzoate 2 mg

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

10 ml
32 ml
100 ml

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

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

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 AND OTHER SUBSTANCES

1 ml contains: meloxicam 5 mg and excipient ethanol 150 mg

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

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP
Shelf-life of broached vial: 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: meloxicam 5 mg and excipient ethanol 150 mg

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

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP
Shelf-life of broached vial: 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 AND OTHER SUBSTANCES

Meloxicam 20 mg/ml
Ethanol 150 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs, horses

6. INDICATION(S)

Read the package leaflet before use.

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

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
Shelf-life of broached vial: 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 AND OTHER SUBSTANCES

Meloxicam 20 mg/ml
Ethanol 150 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs, horses

6. INDICATION(S)

Read the package leaflet before use.

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

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
Shelf-life of broached vial: 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/2/06/070/006
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)

Meloxicam 20 mg /ml
Ethanol 150 mg /ml

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

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}
Shelf-life of broached vial: 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 AND OTHER SUBSTANCES

1 ml contains:
Meloxicam 0.5 mg
Sodium benzoate 2 mg

3. PHARMACEUTICAL FORM

Oral suspension.

4. PACKAGE SIZE

15 ml
5 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening: 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

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 FOR
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.

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

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.
If you notice any serious effects or others effects not mentioned in this leaflet, please inform your veterinary surgeon.

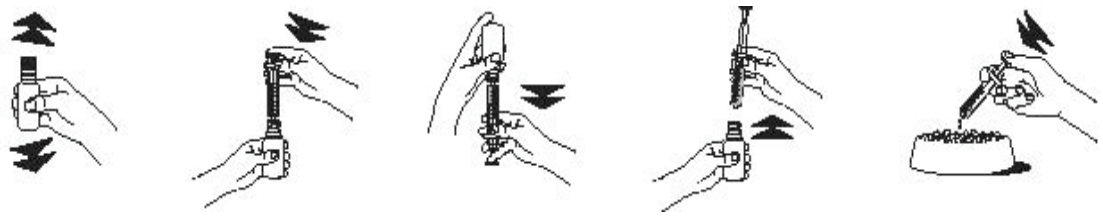
7. TARGET SPECIES

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

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Shelf life of opened bottle: 6 months.
Do not use after the expiry date stated on the carton and the bottle.

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 glucocortisosteroids.
- 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 overdosage, 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 FOR
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:
Ceva Santé Animale –10 avenue de la Ballastière – 33500 Libourne - France

Manufacturer responsible for batch release:
ACCORD HEALTHCARE LIMITED - Sage House - 319 Pinner Road – Harrow – Middlesex
HA1 4HF – UK

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.If you notice any serious effects or other effects not mentioned in this leaflet, 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

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.
Do not use after the expiry date stated on the cardboard box and the vial after EXP.
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.

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.

Precautions to be taken by the person administering the product
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.

Use during pregnancy and lactation
See section “Contraindications”

Interactions
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.

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

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 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 FOR
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 toxaemia (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.

If you notice any serious effects or other effects not mentioned in this leaflet, 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

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 after the expiry date which is stated on the cardboard box and vial after EXP.
Shelf-life after first opening the vial: 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.

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.

Precautions to be taken by the person administering the product
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.

Use during pregnancy and lactation
Cattle and pigs**:** Can be used during pregnancy and lactation.
Horses: See section "Contraindications".

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

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

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 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 FOR:
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
Sodium benzoate	2 mg

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.

If you notice any serious effects or other effects not mentioned in this leaflet, 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

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 after the expiry date stated on the label and the cardboard box after EXP.
Shelf-life after first opening: 6 months.

12. SPECIAL WARNING(S)

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.

Precautions to be taken by the person administering the product
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.

Use during pregnancy and lactation
See section “Contraindications”.

Interactions
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
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.

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 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.