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

Each ml contains:

Active substance:
Meloxicam 1.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of he veterinary medicinal product**
Sodium benzoate (E211)	2 mg
Xanthan gum	
Silica colloidal anhydrous	
Sorbitol liquid non-crystallising	
Glycerol	
Xylitol	
Citric acid anhydrous	
Purified water	

Pale yellow suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of individual hypersensitivity to the product.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1], blood in faeces[1,2], , gastric ulcer[1], small intestine ulcer[1], Appetite loss[1], lethargy[1]

[1]These adverse events occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal..
[2]Occult

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

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

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal 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 veterinary medicinal products used previously.

3.9 Administration routes and dosage

Oral 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. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

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.
Shake well before use.

Avoid introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures andantidotes)

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

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

4.3 Pharmacokinetics

Absorption
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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

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

5.4 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.

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

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

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/070/001
EU/2/06/070/002
EU/2/06/070/003

8. DATE OF THE FIRST AUTHORISATION

Date of first authorisation: 15/01/2007

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF THE VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam 5 mg

Excipients:

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

Clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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

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

3.3 Contraindications

Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals less than 6 weeks of age nor in cats of less than 2 kg.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.
Any oral follow-up therapy using meloxicam or other Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain.
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1], blood in faeces[1,2], [1], gastric ulcer[1], small intestine ulcer[1] Appetite loss[1], lethargy[1] Renal failure[1] Anaphylactoid reaction[1]

[1] In dogs, these adverse events occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
[2]Occult

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

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

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects.
Meloxidyl must not be administered in conjunction with other NSAIDs or glucocorticosteroids.
Concurrent administration of potential nephrotoxic drugs should be avoided.

In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.
Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

3.9 Administration routes and dosage

Dogs:
Musculo-skeletal disorders:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).
Meloxidyl 1.5 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours):
Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

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

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

Avoid introduction of contamination during use.

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

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

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

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

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

4.3 Pharmacokinetics

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

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

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

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

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

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/070/004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 15/01/2007

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam 20 mg

Excipient:

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

Clear, colourless to yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs and horses

3.2 Indications for use for each 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.

3.3 Contraindications

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 cases 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.

3.4 Special warnings

Treatment of calves with the veterinary medicinal product 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1] Injection site swelling[2]

[1] May be serious or fatal and should be treated symptomatically
[2] Following subcutaneous administration

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1] Injection site swelling[2]

[1] May be serious or fatal and should be treated symptomatically
[2] Slight and transient

Horse:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1] Injection site swelling[2]

[1] May be serious or fatal and should be treated symptomatically
[2] Transient, resolving spontaneously

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

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

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation

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.

3.8 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.

3.9 Administration routes and dosage

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).

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

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

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

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

Not applicable.

3.12 Withdrawal periods

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

Pigs:
Meat and offal: 5 days.

Horses:
Meat and offal: 5 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, 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.

4.3 Pharmacokinetics

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, Cmaxvalues of 2.1 mcg/ml and 2.7 mcg/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 mcg/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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

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

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 15/01/2007

9 DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl 0.5 mg/ml oral suspension for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam 0.5 mg

Excipient:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration oft he veterinary medicinal product**
Sodium benzoate (E 211)	2.0 mg
Xanthan gum	
Silica colloidal anhydrous	
Sorbitol liquid non-crystallising	
Glycerol	
Xylitol	
Citric acid anhydrous	
Purified water	

Pale yellow suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each 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.

3.3 Contraindications

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 cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1], blood in faeces[1,2], , gastric ulcer[1], small intestine ulcer[1] Appetite loss[1], lethargy[1] Renal failure[1]

[1]These adverse events occur generally within the first treatment week and are in most cases transients and disappear following termination of the treatment but in very rare cases may be serious or fatal.
[2] Occult
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxidyl must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided.

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.

3.9 Administration routes and dosage

Oral use.

Dosage
Post-operative pain and inflammation following surgical procedures:
After initial treatment with meloxicam solution for injection for cats, continue treatment 24 hours later with the veterinary medicinal product 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. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.
Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

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

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 3.6, are expected to be more severe and more frequent. In the case of overdose, symptomatic treatment should be initiated.

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

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. In vitro and in vivo studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

4.3 Pharmacokinetics

Absorption
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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

7. MARKETING AUTHORISATION NUMBER(S)

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

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 15/01/2007

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

1.5 mg/ml of meloxicam

3. PACKAGE SIZE

10 ml + 2 measuring syringes
32 ml + 2 measuring syringes
100 ml + 2 measuring syringes

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use
Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAMEOF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/070/001 10 ml
EU/2/06/070/002 32 ml
EU/2/06/070/003 100 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 10 ml, 32 ml and 100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1.5 mg/ml of meloxicam

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyy}
Once opened use within 6 months.

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

2. STATEMENT OF ACTIVE SUBSTANCES

5 mg/ml meloxicam.

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs, cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: intravenous or subcutaneous use
Cats: subcutaneous use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25° C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/070/004 10 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 10 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl


2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 mg/ml of meloxicam.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

20 mg/ml of meloxicam.

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs, horses

5. INDICATIONS

6. METHOD AND ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days; Milk: 5 days.
Pigs: Meat and offal: 5 days.
Horses: Meat and offal: 5 days.
Not authorised for use in animals producing milk for human consumption.

80. EXPIRY DATE

Exp. {mm/yyy}
Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/070/005 50 ml
EU/2/06/070/006 100 ml
EU/2/06/070/007 250 ml

15. BATCH NUMBER

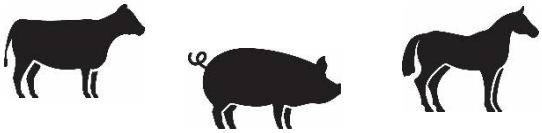
Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label of 100 ml and 250 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl



2. STATEMENT OF ACTIVE SUBSTANCES

20 mg/ml of meloxicam.

3. TARGET SPECIES

Cattle, pigs, horses

4. ROUTES OF ADMINISTRATION

Cattle: Subcutaneous or Intravenous use
Pigs: Intramuscular use
Horses: Intravenous use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days; Milk: 5 days.
Pigs: Meat and offal: 5 days.
Horses: Meat and offal: 5 days.
Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

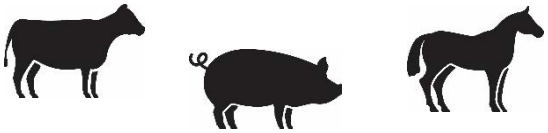
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 mg/ml of meloxicam.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyy}
Once broached, use within 28 days.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 5 ml and 15 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl 0.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

0.5 mg/ml of meloxicam.

3. PACKAGE SIZE

15 ml + one measuring syringe
5 ml + one measuring syringe

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Shake well before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/070/008 15 ml
EU/2/06/070/010 5 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label of 5 ml and 15 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxidyl

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.5 mg/ml of meloxicam.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Meloxidyl 1.5 mg/ml oral suspension for dogs

2. Composition

Each ml contains:

Active substance:
Meloxicam 1.5 mg

Excipient:
Sodium benzoate (E211) 2 mg

Pale yellow suspension

3. Target species

Dogs.

4. Indications for use

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

5. Contraindications

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. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species
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 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.

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

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 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.

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

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1], diarrhoea[1], blood in faeces [1,2], gastric ulcer[1], small intestine ulcer[1] Appetite loss[1], lethargy

[1]These adverse events occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
[2]Occult

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral 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.

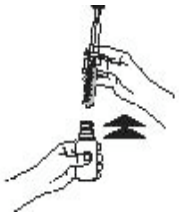
The suspension can be given using the measuring syringes provided in the package. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1mg Meloxicam/kg body weight). Thus, for the first day, twice the maintenance volume will be required.

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

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

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 periods

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 carton and the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

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

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/06/070/001
EU/2/06/070/002
EU/2/06/070/003

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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France
Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer 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

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

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

2. Composition

One ml contains:

Active substance:
Meloxicam 5 mg.

Excipients:
Ethanol anhydrous 150 mg

Clear, yellow solution.

3. Target species

Dogs, cats.


4. Indications for use

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 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. Special warnings

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

Special precautions for safe use use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Any oral follow-up therapy using meloxicam or other 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:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating animals.

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. Meloxidylmust 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.

Major incompatibilities
None known.

7. Adverse events

Cats, dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Vomiting[1], diarrhoea[1], blood in faeces [1,2], gastric ulcer[1], small intestine ulcer[1] Appetite loss[1], lethargy[1] Renal failure[1] Anaphylactoid reaction[1]

[1] In dogs, these adverse enevnts 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.
[2]Occult

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report

any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes 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:
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. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

10. Withdrawal periods

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 immediate packaging: 28 days.

12. Special precautions for disposal

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/06/070/004

Pack size:
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.

15. Date on which the package leaflet was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Ceva Santé Animale,
10 av. de La Ballastière, 33500 Libourne, France
Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

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

2. Composition

One ml contains:

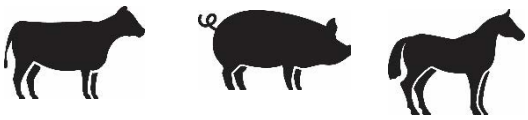
Active substances:
Meloxicam 20 mg

Excipients:
Ethanol anhydrous 150 mg

Clear, colourless to yellowish solution.

3. Target species

Cattle, pigs and horses.



4. Indications for use

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 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 cases 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. Special warnings

Special warnings
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 safe use in the target species:
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:
Do not use in pregnant or lactating mares.
Do not use in horses producing milk for human consumption.

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

Major incompatibilities
None known.

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactoid reaction[1] Injection site swelling[2]

[1] May be serious or fatal and should be treated symptomatically
[2] Following subcutaneous administration

Pig:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactoid reaction[1] Injection site swelling[2]

[1] May be serious or fatal and should be treated symptomatically
[2] Slight and transient

Horse:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactoid reaction[1] Injection site swelling[2]
Undetermined frequency (cannot be estimated from the available data)

[1] May be serious or fatal and should be treated symptomatically
[2]Transient, resolving spontaneously

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes 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 periods

Cattle: meat and offal: 15 days; milk: 5 days
Pigs: meat and offal: 5 days
Horses: meat and offal: 5 days
Not authorised for use in animals producing milk for human consumption.

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 immediate packaging: 28 days.

12. Special precautions for disposal

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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

Pack size:
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.

15. Date on which the package leaflet was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions
Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France
Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Meloxidyl 0.5 mg/ml oral suspension for cats

2. Composition

One ml contains:

Active substance:
Meloxicam 0.5 mg

Excipients:
Sodium benzoate (E 211) 2.0 mg

Pale yellow suspension

3. Target species

Cats.

4. Indications for use

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

6. Special warnings

Special warnings:
None

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of 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:
Do not use in pregnant or lactating animals.

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:
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 events” are expected to be more severe and more frequent. In the case of overdose, symptomatic treatment should be initiated.

Major incompatibilities
None known.

7. Adverse events

Cat:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Vomiting[1], diarrhoea[1], blood in faeces[1,2] ;gastric ulcer[1], small intestine ulcer[1] Appetite loss[1], lethargy[1] Renal failure[1]

[1]These adverse events occur generally within the first treatment week and are in most cases transients and disappear following termination of the treatment but in very rare cases may be serious or fatal.
[2] Occult

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

Dosage
Post-operative pain and inflammation following surgical procedures:
After initial treatment with meloxicam 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
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

Shake well before use. Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.
Please carefully follow the instructions of the veterinarian.

10. Withdrawal periods

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 immediate packaging: 6 months.

12. Special precautions for disposal

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

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

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.

15. Date on which the package leaflet was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Ceva Santé Animale, 10 av. de La Ballastière, 33500 Libourne, France
Tel: +800 35 22 11 51
E-mail: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, Z.I. Très le Bois**,** 22600 Loudéac, France