ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral 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 the veterinary medicinal product**
Sodium benzoate	1.75 mg
Sorbitol	
Glycerol	
Polysorbate 80	
Disodium phosphate dodecahydrate	
Silica, colloidal anhydrous	
Hydroxyethylcellulose	
Citric acid monohydrate	
Sodium cyclamate	
Sucralose	
Anise aroma	
Water, purified	

Yellow/ green 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 in dogs.

3.3 Contraindications

Do not use in dogs 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 dogs less than 6 weeks of age.
See section 3.7.

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 increased renal toxicity.

This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Meloxoral 0.5 mg/ml oral suspension for cats should be used.

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 treated, including isolated reports):	Appetite loss[1], Apathy[1] Vomiting[1], Diarrhoea[1], Blood in faeces[1,2], Haemorrhagic diarrhoea[1], Haematemesis[1], Gastric ulcer[1], Small intestine ulcer[1], Large intestine ulcer[1] Renal failure[1] Elevated liver enzymes[1]

[1] These reactions 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 adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
[2] occult

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 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. Meloxoral 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 veterinary medicinal products 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

Oral use.

To be administered either mixed with food or directly into the mouth.
Shake well before use.

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.

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of Meloxoral can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

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

The suspension can be given using the measuring syringe provided in the package.
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

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.

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

In 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
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 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

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: 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

Cardboard box with 1 polyethylene bottle closed with a tamper proof child resistant closure and a polypropylene measuring syringe.

Pack sizes:
Cardboard box with one bottle of 10 ml.
Cardboard box with one bottle of 25 ml.
Cardboard box with one bottle of 50 ml.
Cardboard box with one bottle of 125 ml.

Cardboard box with one bottle of 180 ml.

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/111/005 10 ml
EU/2/10/111/001 25 ml
EU/2/10/111/002 50 ml
EU/2/10/111/003 125 ml
EU/2/10/111/008 180 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 19/11/2010.

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

Meloxoral 0.5 mg/ml oral suspension for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:

Meloxicam 0.5 mg.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate	1.75 mg
Sorbitol	
Glycerol	
Polysorbate 80	
Disodium phosphate dodecahydrate	
Silica, colloidal anhydrous	
Hydroxyethylcellulose	
Citric acid monohydrate	
Sodium cyclamate	
Sucralose	
Anise aroma	
Water, purified	

Yellow/ green suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

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 case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks of age.
See section 3.7.

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.

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.

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

3.6 Adverse events

Cats:

Very Rare (<1 animal / 10,000 treated, including isolated reports):	Appetite loss[1], Apathy[1] Vomiting[1], Diarrhoea[1], Renal failure[1] Elevated liver enzymes[1]
Undetermined frequency (cannot be estimated from the available data)	Blood in faeces[1, 2]

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

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 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. Meloxoral must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products 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 veterinary medicinal products 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

Oral use.

To be administered either mixed with food or directly into the mouth.
Shake well before use.

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.

The suspension can be given using the measuring syringe provided in the package. The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.
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.

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 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. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive. As for other species investigated, the main pathway of meloxicam biotransformation in cat is oxidation.

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. 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: 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

Cardboard box with 1 polyethylene bottle closed with a tamper proof child resistant closure and a polypropylene measuring syringe.

Pack sizes:
Cardboard box with one bottle of 5 ml.
Cardboard box with one bottle of 10 ml.
Cardboard box with one bottle of 25 ml.

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/10/111/007 5 ml
EU/2/10/111/006 10 ml
EU/2/10/111/004 25 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 19/11/2010.

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

Meloxoral 1.0 mg chewable tablets for dogs
Meloxoral 2.5 mg chewable tablets for dogs
Meloxoral 4.0 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:
Meloxoral 1.0 mg chewable tablets
Meloxicam 1.0 mg

Meloxoral 2.5 mg chewable tablets
Meloxicam 2.5 mg

Meloxoral 4.0 mg chewable tablets
Meloxicam 4.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium citrate	
Lactose monohydrate	
Cellulose, microcrystalline	
Chicken flavor	
Yeast (dried)	
Crospovidone	
Sillica, colloidal hydrated	
Magnesium stearate	

Meloxoral 1.0 mg chewable tablets
Light brown with brown spots, round and convex 11 mm chewable tablet with a cross-shaped break line on one side.
The chewable tablet can be divided into 2 or 4 equal doses.

Meloxoral 2.5 mg chewable tablets
Light brown with brown spots, round and convex 16 mm chewable tablet with a cross-shaped break line on one side.
The chewable tablet can be divided into 2 or 4 equal doses.

Meloxoral 4.0 mg chewable tablets
Light brown with brown spots, round and convex 19 mm chewable tablet with a cross-shaped break line on one side.
The chewable tablet can be divided into 2 or 4 equal doses.

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 musculoskeletal disorders.

3.3 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 dogs less than 6 weeks of age or less than 1.7 kg in bodyweight.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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, hypovolemic or hypotensive animal, as there is a potential risk of renal toxicity.
This veterinary medicinal product for dogs should not be used in cats as it is not suitable for use in this species. In cats meloxicam 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or to any of the excipients should avoid contact with the veterinary medicinal product.
Accidental ingestion, especially by children, may cause adverse reactions. Unused tablet parts should be placed back into the blister and carton and carefully kept away from children. In case of accidental ingestion by a child seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

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

3.6 Adverse events

Dogs:

Very Rare (<1 animal / 10,000 treated, including isolated reports):	Appetite loss[1], Apathy[1] Vomiting[1], Diarrhoea[1], Blood in faeces[1,2], Haemorrhagic diarrhoea[1], Haematemesis[1], Gastric ulcer[1], Small intestine ulcer[1], Large intestine ulcer[1] Renal failure[1] Elevated liver enzymes[1]

[1] These reactions 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

adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
[2] occult

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 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 (see section 3.3).

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. This 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 veterinary medicinal products 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.

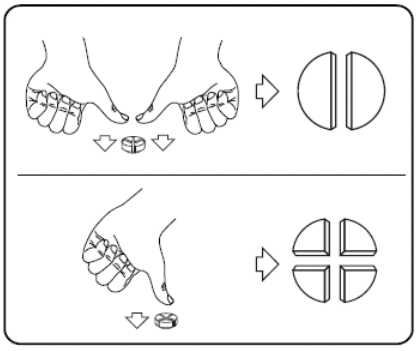
Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day.

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 veterinary medicinal product is flavored and can be administered with or without food.

Each chewable tablet contains 1.0, 2.5 or 4.0 mg meloxicam, which corresponds to the daily maintenance dose for a 10, 25, or 40 kg dog.

Each chewable tablet can be halved or quartered for accurate dosing according to the individual body weight of the animal.
Place the chewable tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halved chewable tablets: press down with your thumbs on both sides of the tablet.
Quartered chewable tablets: press down with your thumb in the middle of the tablet.

Dose scheme for the maintenance dose of 0.1 mg/kg (double dose first day):

Body weight (Kg)	Number of chewable tablets using			Dose in mg/kg
	1 mg	2.5 mg	4 mg	
1.7-3.2	¼			0.15-0.1
3.3-5.0	½			0.15-0.1
5.1-7.5	¾			0.15-0.1
7.6-10.0	1			0.13-0.1
10.1-12.5	1 ¼			0.12-0.1
12.6-15.0	1½			0.12-0.1
15.1-20.0	2			0.13-0.1
9.0-12.5		½		0.14-0.1
12.6-18.7		¾		0.15-0.1
18.8-25.0		1		0.13-0.1
25.1-31.2		1¼		0.12-0.1
31.3-37.5		1½		0.12-0.1
37.6-50.0		2		0.13-0.1
15.0-20.0			½	0.13-0.1
20.1-30.0			¾	0.15-0.1
30.1-40.0			1	0.13-0.1
40.1-50.0			1¼	0.12-0.1
50.1-60.0			1½	0.12-0.1
60.1-80.0			2	0.13-0.1

Depending on the weight of the dog, combination of strengths of Meloxoral chewable tablets for dogs (1.0 mg, 2.5 mg and 4.0 mg) may be considered.

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

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

In case of over dosage 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
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 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 of divided tablets after first opening the immediate packaging: 3 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Any unused tablet parts should be returned to the open blister and carton.

5.4 Nature and composition of immediate packaging

Meloxoral 1.0 mg chewable tablets
Meloxoral 2.5 mg chewable tablets
OPA/Aluminium/PVC//PVC-PVDC/Aluminium blisters containing 10 tablets in a cardboard box.

Meloxoral 4.0 mg chewable tablets
OPA/Aluminium/PVC//PVC-PVDC/Aluminium blisters containing 5 tablets in a cardboard box.

Pack sizes:

Cardboard box of 30, 50 or 100 tablets.

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER(S)

Meloxoral 1.0 mg chewable tablets for dogs:
EU/2/10/111/009 30 tablets
EU/2/10/111/010 50 tablets
EU/2/10/111/011 100 tablets

Meloxoral 2.5 mg chewable tablets for dogs:
EU/2/10/111/012 30 tablets
EU/2/10/111/013 50 tablets
EU/2/10/111/014 100 tablets

Meloxoral 4.0 mg chewable tablets for dogs:
EU/2/10/111/015 30 tablets
EU/2/10/111/016 50 tablets
EU/2/10/111/017 100 tablets

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 30.11.2022.

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Meloxicam 1.5 mg.

3. PACKAGE SIZE

10 ml
25 ml
50 ml
125 ml
180 ml

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.
Once broached, use by…

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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/111/005 10 ml
EU/2/10/111/001 25 ml
EU/2/10/111/002 50 ml
EU/2/10/111/003 125 ml
EU/2/10/111/008 180 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle 125 ml or 180 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. TARGET SPECIES

Dogs 

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months.
Once broached, use by…

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 10, 25 or 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months.
Once broached, use by…

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral 0.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Meloxicam 0.5 mg

3. PACKAGE SIZE

5 ml
10 ml
25 ml

4. TARGET SPECIES

Cats 

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Shake well before use.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months.
Once broached, use by…

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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/111/007 5 ml
EU/2/10/111/006 10 ml
EU/2/10/111/004 25 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 5, 10 or 25 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 0.5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 6 months.
Once broached, use by…

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral 1.0 mg chewable tablets
Meloxoral 2.5 mg chewable tablets
Meloxoral 4.0 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.0 mg
Meloxicam 2.5 mg
Meloxicam 4.0 mg

3. PACKAGE SIZE

30 chewable tablets
50 chewable tablets
100 chewable tablets

4. TARGET SPECIES

Dogs 

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life of divided tablets after first opening the immediate packaging: 3 days.

9. SPECIAL STORAGE PRECAUTIONS

Any unused chewable tablet parts should be returned to the open blister and carton.

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

Dechra Regulatory BV

14. MARKETING AUTHORISATION NUMBERS

EU/2/10/111/009 30 tablets
EU/2/10/111/010 50 tablets
EU/2/10/111/011 100 tablets

EU/2/10/111/012 30 tablets
EU/2/10/111/013 50 tablets
EU/2/10/111/014 100 tablets

EU/2/10/111/015 30 tablets
EU/2/10/111/016 50 tablets
EU/2/10/111/017 100 tablets

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE SMALL IMMEDIATE PACKAGE

ALUMINIUM BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meloxoral
Meloxoral
Meloxoral

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 1.0 mg
Meloxicam 2.5 mg
Meloxicam 4.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life of divided tablets after first opening the immediate packaging: 3 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Meloxoral 1.5 mg/ml oral suspension for dogs

2. Composition

Each ml contains:

Active substance:
Meloxicam 1.5 mg.

Excipients:
Sodium benzoate 1.75 mg

Yellow/ green 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 dogs 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 dogs less than 6 weeks of age.

6. Special warnings

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.
This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Meloxoral 0.5 mg/ml oral suspension for cats should be used.

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 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. Meloxoral 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 veterinary medicinal products 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:
In case of overdose symptomatic treatment should be initiated.

7. Adverse events

Dogs:

Very Rare (<1 animal / 10,000 treated, including isolated reports):	Appetite loss[1], Apathy[1] Vomiting[1], Diarrhoea[1], Blood in faeces[1,2], Haemorrhagic diarrhoea[1], Haematemesis[1], Gastric ulcer[1], Small intestine ulcer[1], Large intestine ulcer[1] Renal failure[1] Elevated liver enzymes[1]

[1] These reactions 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 adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
[2] occult

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 either mixed with food or directly into the mouth.

Dosage
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.

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of Meloxoral can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

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.

9. Advice on correct administration

Shake well before use.
The suspension can be given using the Meloxoral measuring syringe provided in the package.

The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

After each dose, the tip of the syringe should be wiped and the bottle cap screwed back on tightly. The syringe should be stored in the carton box in between uses.
To avoid introduction of external contaminants during use, keep the provided syringes only for this product.

Particular care should be taken with regard to the accuracy of dosing. 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 carton and the bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/10/111/005 10 ml

EU/2/10/111/001 25 ml
EU/2/10/111/002 50 ml
EU/2/10/111/003 125 ml
EU/2/10/111/008 180 ml

Cardboard box containing one bottle of 10, 25, 50, 125 or 180 ml.
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:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands
Tel.: +31 348 563434

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Meloxoral 0.5 mg/ml oral suspension for cats

2. Composition

Each ml contains:

Active substance:
Meloxicam 0.5 mg.

Excipient:
Sodium benzoate 1.75 mg
Yellow/ green suspension.

3. Target species

Cats 

4. Indications for use

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 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. Special warnings

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

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 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. Meloxoral must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products 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 veterinary medicinal products 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.

7. Adverse events

Cats:

Very Rare (<1 animal / 10,000 treated, including isolated reports):	Appetite loss[1], Apathy[1] Vomiting[1], Diarrhoea[1], Renal failure[1] Elevated liver enzymes[1]
Undetermined frequency (cannot be estimated from the available data)	Blood in faeces[1, 2]

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

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 orally either mixed with food or directly into the mouth.

Dosage
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.

9. Advice on correct administration

Shake well before use.

The suspension can be given using the Meloxoral measuring syringe provided in the package.

The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

After each dose, the tip of the syringe should be wiped and the bottle cap screwed back on tightly. The syringe should be stored in the carton box in between uses.
To avoid introduction of external contaminants during use, keep the provided syringes only for this product.

Particular care should be taken with regard to the accuracy of dosing. 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 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.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/10/111/007 5 ml
EU/2/10/111/006 10 ml
EU/2/10/111/004 25 ml

Cardboard box containing one bottle of 5, 10 or 25 ml.

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:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands
Tel.: +31 348 563434

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Meloxoral 1.0 mg chewable tablets for dogs
Meloxoral 2.5 mg chewable tablets for dogs
Meloxoral 4.0 mg chewable tablets for dogs

2. Composition

Each chewable tablet contains:

Active substance:
Meloxoral 1.0 mg chewable tablets
Meloxicam 1.0 mg

Meloxoral 2.5 mg chewable tablets
Meloxicam 2.5 mg

Meloxoral 4.0 mg chewable tablets
Meloxicam 4.0 mg

Meloxoral 1.0 mg chewable tablets
Chewable tablet.
Light brown with brown spots, round and convex 11 mm tablet with a cross-shaped break line on one side.
The chewable tablet can be divided into 2 or 4 equal doses.

Meloxoral 2.5 mg chewable tablets
Chewable tablet.
Light brown with brown spots, round and convex 16 mm tablet with a cross-shaped break line on one side.
The chewable tablet can be divided into 2 or 4 equal doses.

Meloxoral 4.0 mg chewable tablets
Chewable tablet.
Light brown with brown spots, round and convex 19 mm tablet with a cross-shaped break line on one side.
The chewable tablet can be divided into 2 or 4 equal doses.

3. Target species

Dogs 

4. Indications for use

Alleviation of inflammation and pain in both acute and chronic musculoskeletal disorders.

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 dogs less than 6 weeks of age or less than 1.7 kg in bodyweight.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

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.
This veterinary medicinal product for dogs should not be used in cats as it is not suitable for use in this species. In cats meloxicam 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or to any of the excipients should avoid contact with the veterinary medicinal product.
Accidental ingestion, especially by children, may cause adverse reactions. Unused tablet parts should be placed back into the blister and carton and carefully kept away from children. In case of accidental ingestion by a child seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

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. This 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 veterinary medicinal products 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:
In case of over dosage symptomatic treatment should be initiated.

7. Adverse events

Dogs:Very Rare (<1 animal / 10,000 treated, including isolated reports):	Appetite loss[1], Apathy[1] Vomiting[1], Diarrhoea[1], Blood in faeces[1,2], Haemorrhagic diarrhoea[1], Haematemesis[1], Gastric ulcer[1], Small intestine ulcer[1], Large intestine ulcer[1] Renal failure[1] Elevated liver enzymes[1]

[1] These reactions 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

adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
[2] occult

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.

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 veterinary medicinal product is flavored and can be administered with or without food.

Each tablet contains 1.0, 2.5 or 4.0 mg meloxicam, which corresponds to the daily maintenance dose for a 10, 25, or 40 kg dog.

Dose scheme for the maintenance dose of 0.1 mg/kg (double dose first day):

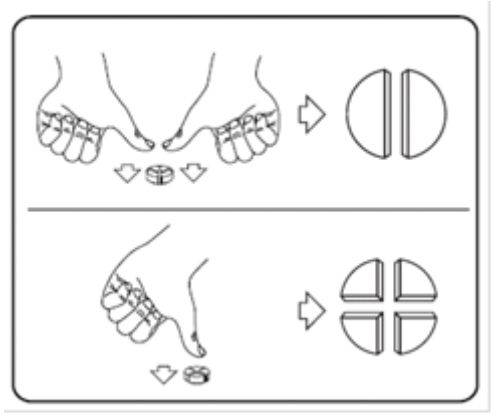
Body weight (Kg)	**Number of tablets using**			**Dose in mg/kg**
	1 mg	**2.5 mg**	**4 mg**	
1.7-3.2	¼			0.15-0.1
3.3-5.0	½			0.15-0.1
5.1-7.5	¾			0.15-0.1
7.6-10.0	1			0.13-0.1
10.1-12.5	1 ¼			0.12-0.1
12.6-15.0	1½			0.12-0.1
15.1-20.0	2			0.13-0.1
9.0-12.5		½		0.14-0.1
12.6-18.7		¾		0.15-0.1
18.8-25.0		1		0.13-0.1
25.1-31.2		1¼		0.12-0.1
31.3-37.5		1½		0.12-0.1
37.6-50.0		2		0.13-0.1
15.0-20.0			½	0.13-0.1
20.1-30.0			¾	0.15-0.1
30.1-40.0			1	0.13-0.1
40.1-50.0			1¼	0.12-0.1
50.1-60.0			1½	0.12-0.1
60.1-80.0			2	0.13-0.1

Depending on the weight of the dog, combination of strengths of Meloxoral chewable tablets for dogs (1.0 mg, 2.5 mg and 4.0 mg) may be considered.

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

9. Advice on correct administration

Each tablet can be halved or quartered for accurate dosing according to the individual body weight of the animal.
Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



Halved tablets: press down with your thumbs on both sides of the tablet.
Quartered tablets: press down with your thumb in the middle of the tablet.

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 blister after Exp. The expiry date refers to the last day of that month.

Shelf life of divided tablets after first opening the immediate packaging: 3 days.
Any unused tablet parts should be returned to the open blister and carton.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Meloxoral 1.0 mg chewable tablets for dogs:
EU/2/10/111/009 30 tablets
EU/2/10/111/010 50 tablets
EU/2/10/111/011 100 tablets

Meloxoral 2.5 mg chewable tablets for dogs:
EU/2/10/111/012 30 tablets
EU/2/10/111/013 50 tablets
EU/2/10/111/014 100 tablets

Meloxoral 4.0 mg chewable tablets for dogs:
EU/2/10/111/015 30 tablets
EU/2/10/111/016 50 tablets
EU/2/10/111/017 100 tablets

Cardboard box of 30, 50 or 100 chewable tablets.

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:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands
Tel.: +31 348 563434

Manufacturer responsible for batch release:
Lelypharma BV
Zuiveringweg 42
8243 PZ Lelystad
The Netherlands