

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 the 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
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¹These 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..

²Occult

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. 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 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

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).