

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 5 mg.

Excipients:

Ethanol anhydrous 150 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

Dogs:

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

Cats:

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

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

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

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

Any oral follow-up therapy using meloxicam or other Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

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

Accidental self-injection may give rise to pain.

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

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

4.6 Adverse reactions (frequency and seriousness)

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally been reported.

In dogs, these side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects.

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

Concurrent administration of potential nephrotoxic drugs should be avoided.

In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

4.9 Amounts to be administered and administration route

Dogs:

Musculo-skeletal disorders:

Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).

Meloxidyl 1.5 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours):

Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

Cats:

Reduction of post-operative pain:

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

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

Avoid introduction of contamination during use.

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

In the case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams)
ATC-vet code: QM01AC06

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

Absorption

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

Distribution

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

Metabolism

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

Elimination

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

6.4. Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

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

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

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

7. MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10 avenue de la Ballastière
33500 Libourne
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/06/070/004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15.01.2007

Date of last renewal: 19.12.2011

10. DATE OF REVISION OF THE TEXT

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

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.