

PACKAGE INSERT**VETERINARY MEDICINE****SCHEDULING STATUS****S3****PROPRIETARY NAME AND DOSAGE FORM****Loxicom 0,5 mg/ml Oral Suspension****Loxicom 1,5 mg/ml Oral Suspension****COMPOSITION*****Loxicom 0,5 mg/ml Oral Suspension:***

Each ml contains 0,5 mg meloxicam (micronized).

Sodium Benzoate 0,15 % w/w (preservative)

Loxicom 1,5 mg/ml Oral Suspension:

Each ml contains 1,5 mg meloxicam (micronized).

Sodium Benzoate 0,15 % w/w (preservative)

Other ingredients include citric acid anhydrous, disodium phosphate dihydrate, glycerol, povidone K30, simethicone emulsion, sodium benzoate, sodium dihydrogen phosphate dihydrate, water for injection and xanthan gum.

PHARMACOLOGICAL CLASSIFICATION

C.3.1.2.2 Selective COX-2 inhibitors

PHARMACOLOGICAL ACTION***Pharmacodynamic properties***

Meloxicam is a non-steroidal anti-inflammatory compound of the oxicam group, which acts by inhibition of prostaglandin synthesis.

It exerts anti-inflammatory, analgesic, anti-exudative and antipyretic effects, inhibits leukocyte infiltration into the inflamed tissue and prevents bone and cartilage destruction. To a minor extent, it also inhibits collagen-induced thrombocyte aggregation.

Pharmacokinetic properties

Absorption

Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after 2 to 4,5 hours. Steady state concentrations of meloxicam in plasma are reached within 3 to 5 days after repeated once daily administration.

Distribution

There is a linear relationship between the dose administered and the plasma concentration observed in the therapeutic dose range. Approximately 97 % of meloxicam is bound to plasma proteins.

Metabolism

Meloxicam is predominant in plasma (> 80 %), whereas urine, bile and faeces contain only traces of the parent compound. It 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 excreted via faeces and the remainder via urine mostly as pharmacologically inactive metabolites.

INDICATIONS

Indicated for the alleviation of inflammation and pain in both acute and chronic musculoskeletal disorders such as disco-spondylitis, arthropathy and soft tissue injuries in dogs.

CONTRAINDICATIONS

Do not use in case of hypersensitivity to meloxicam or to any of the excipients.

Loxicom Oral Suspension should not be used in cats.

Do not use in pregnant or lactating dogs (see PREGNANCY AND LACTATION).

The use of **Loxicom Oral Suspension** is contraindicated in animals suffering from cardiac, hepatic or clinical renal disease, gastrointestinal ulceration and haemorrhagic diathesis.

WARNINGS AND SPECIAL PRECAUTIONS

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

The use of **Loxicom Oral Suspension** in any animal less than 6 weeks of age or in debilitated aged animals may involve additional risk. If use in such animals cannot be avoided, a reduced dosage and careful clinical management is required.

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

Special precautions to be taken by the person administering Loxicom Oral Suspension to animals

People with known hypersensitivity to meloxicam or other non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with **Loxicom Oral Suspension**. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to your doctor or pharmacist.

INTERACTIONS

Loxicom Oral Suspension should not be administered concurrently or following pre-treatment with other steroidal or non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticosteroids, diuretics, aminoglycoside antibiotics or anticoagulant agents and substances with high protein binding, which may compete for protein binding and thus lead to toxic effects.

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

PREGNANCY AND LACTATION

Do not use in pregnant or lactating dogs (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

For oral use only.

Shake well before use.

Loxicom Oral Suspension should be administered orally either mixed with food or directly into the mouth.

Initial treatment is a single dose of 0,2 mg/kg body weight (i.e. 4 ml/10 kg bodyweight of **Loxicom 0,5 mg/ml Oral Suspension** or 1,33 ml/10 kg body weight of **Loxicom 1,5 mg/ml Oral Suspension**) on the first day. Treatment is to be continued by once daily oral administration (at 24-hour intervals) at a maintenance dose of 0,1 mg/kg (i.e. 4 ml/10 kg bodyweight of **Loxicom 0,5 mg/ml Oral Suspension** or 0,667 ml/10 kg body weight of **Loxicom 1,5 mg/ml Oral Suspension**) for medium to long-term use.

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

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

The suspension can be given using either of the two measuring syringes provided in the package. The syringes fit onto the bottle and have a kg-bodyweight scale which corresponds to the maintenance dose (i.e. 0,1 mg meloxicam per kg bodyweight). Thus for the first day, twice the maintenance volume will be required. Alternatively therapy may be initiated with meloxicam 5 mg/ml solution for injection.

Follow the instructions of the veterinarian. 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.

The lowest effective dose depends on the individual clinical response of the animal and should be monitored by the veterinarian.

Avoid introduction of contamination during use.

SIDE EFFECTS

Side effects may include loss of appetite, vomiting, diarrhoea, occult blood in the faeces and depression. In very rare cases, haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported. Gastrointestinal side effects are in most cases transient and disappear following termination of treatment, but in rare cases may be serious.

If gastrointestinal side effects occur treatment should be discontinued and the advice of a veterinarian should be sought.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

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

IDENTIFICATION

Loxicom 0,5 mg/ml Oral Suspension: A pale yellow suspension.

Loxicom 1,5 mg/ml Oral Suspension: A pale yellow suspension.

PRESENTATION

Loxicom 0,5 mg/ml Oral Suspension: Clear polyethylene terephthalate (PET) bottles with HDPE/LDPE child-resistant caps, containing 15 ml and 30 ml oral suspension. Two measuring syringes are also provided with the product. Each bottle is packed separately into outer cardboard cartons.

Loxicom 1,5 mg/ml Oral Suspension: Clear polyethylene terephthalate (PET) bottles with HDPE/LDPE child-resistant caps, containing 10 ml, 32 ml, 100 ml and 200 ml oral suspension. Two measuring syringes are also provided with the product. Each bottle is packed separately into outer cardboard cartons.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

The product can be used for 6 months after first opening when stored at or below 25 °C.

For Animal Treatment only.

KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS.

REGISTRATION NUMBERS

Loxicom 0,5 mg/ml Oral Suspension: 09/3.1.2.2/01

Loxicom 1,5 mg/ml Oral Suspension: 09/3.1.2.2/02

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Biotech Laboratories (Pty) Ltd

(Reg. No. 1990/007220/07)

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DATE OF PUBLICATION OF THE PACKAGE INSERT

Loxicom 0,5 mg/ml Oral Suspension: 05 July 2022.

Loxicom 1,5 mg/ml Oral Suspension: 05 July 2022.