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Loxicom 1.5 mg/ml Oral Suspension Dogs

Species:	Dogs
Therapeutic indication:	**Pharmaceuticals: Anti-inflammatory preparations: Oral:** Other NSAIDs
Active ingredient:	Meloxicam
Product:	Loxicom 1.5 mg/ml Oral Suspension Dogs
Product index:	Loxicom 1.5 mg/ml Oral Suspension Dogs
Incorporating:	

Qualitative and quantitative composition

Each ml contains:

Active Substance: Meloxicam 1.5 mg

Excipients: Sodium Benzoate 1.5 mg

Pharmaceutical form

Pale yellow oral suspension.

Clinical particulars

Target species

Dogs.

Indications for use, specifying the target species

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

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 no use in dogs less than 6 weeks of age.

Special warnings for each target species

None.

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 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.

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 very rare cases haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported. These adverse 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.

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

- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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).

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation, (see *contraindications*)

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. Loxicom 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.

Amounts to be administered and administration route

Oral use.

To be administered with food or directly into the mouth.

Shake well before use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg bodyweight (i.e. 1.33 ml/10 kg bodyweight) 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 bodyweight (i.e. 0.667 ml/10 kg bodyweight).

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose 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 either of the two measuring syringes provided in the package (depending on weight of dog). The syringes fit onto the bottle and have a kg-bodyweight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg bodyweight). Thus for the first day, twice the maintenance volume will be required. Alternatively therapy may be initiated with Loxicom 5 mg/ml solution for injection.

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.

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

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

Pharmacological particulars

Pharmacotherapeutic Group: Anti-inflammatory and anti-rheumatic products, non-steroids (oxicams).

ATCvet code: QM01AC06

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).

Pharmacokinetic particulars

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 in dogs. 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.

Pharmaceutical particulars

List of Excipients

- Sodium Benzoate
- Glycerol
- Povidone K30
- Xanthan Gum
- Disodium Phosphate Dihydrate
- Sodium Dihydrogen Phosphate Dihydrate
- Citric Acid Anhydrous
- Simethicone Emulsion
- Purified water

Incompatibilities

None known.

Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months

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

Special precautions for storage

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

Nature and composition of immediate packaging

The veterinary medicinal product is presented in 10 ml, 32 ml, 100 ml and 2 x100ml polyethylene screw bottles with HDPE/LDPE child resistant caps. Two polyethylene/polypropylene measuring syringes, a 1 ml and 5 ml syringe, are supplied with each bottle to ensure accurate dosing of small and large dogs.

Each syringe is graduated in bodyweight, the 1 ml syringe is graduated from 0.5 kg to 15 kg and the 5 ml syringe for 2.5 kg to 75 kg.

Special precautions for the disposal of unused veterinary medicinal product or waste material 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.

Marketing Authorisation Holder (if different from distributor)

Norbrook Laboratories (Ireland) Limited, Rossmore Industrial Estate, Monaghan, Ireland

Marketing Authorisation Number

UK(GB): Vm 02000/5003

UK(NI): EU/2/08/090/003, EU/2/08/090/004, EU/2/08/090/005, EU/2/08/090/032, EU/2/08/090/033

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation: 10/02/2009

Date of last renewal: 23/01/2019

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/.
January 2019

Any other information

Nil.

Legal category

Legal category: POM-V

GTIN

GTIN description: Loxicom 1.5mg/ml for Dogs 10ml

GTIN: 5023534007999

GTIN description: Loxicom 1.5mg/ml for Dogs 32ml

GTIN: 5023534008002

GTIN description: Loxicom 1.5mg/ml for Dogs 100ml

GTIN: 5023534008019

GTIN description: Loxicom 1.5 mg/ml Oral Suspension for Dogs 2 x100ml dual pack

GTIN: 5023534028475