

NOAH Compendium

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[Virbac Limited](#)

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Inflacam 1.5mg/mL oral suspension for dogs

Species: Dogs

Therapeutic indication: Pharmaceuticals: Anti-inflammatory preparations: Oral: Other NSAIDs

Active ingredient: Meloxicam

Product: Inflacam 1.5mg/mL oral suspension for dogs

Product index: Inflacam 1.5mg/mL oral suspension for dogs

Incorporating:

Qualitative and quantitative composition

One ml contains:

Active substance:

Meloxicam 1.5 mg

Excipient:

Sodium benzoate 5 mg.

For the full list of excipients, see section 6.1

Pharmaceutical form

Oral suspension.

A yellow coloured suspension.

Clinical particulars

Target species

Dogs

Indications for use

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

Contra-indications

Do not use in pregnant or lactating animals.

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.

Special warnings for each target species

None

Special precautions for use

Special precautions for use in animals

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

This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Inflacam 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.

Adverse reactions

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. In very rare cases haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported.

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.

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

Use during pregnancy, lactation or lay

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

Interactions

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

Amounts to be administered and administration route

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 Inflacam 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.

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

The suspension can be given using the Inflacam measuring syringe 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 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.

Overdose

In case of overdose symptomatic treatment should be initiated.

Withdrawal periods

Not applicable

Pharmacological particulars

Pharmacotherapeutic group: Anti-inflammatory and Anti-rheumatic products, Non-steroids.

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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 properties

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.

Pharmaceutical particulars

Excipients

Saccharin sodium

Sodium carboxyl methyl cellulose

Colloidal silicon dioxide

Citric acid monohydrate

Sorbitol solution

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Disodium hydrogen-phosphate dodecahydrate

Sodium benzoate

Honey flavour

Purified water.

Major incompatibilities

None known

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

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.

Immediate packaging

15 ml HDPE bottle with a tamper resistant child proof closure or 42, 100 or 200 ml polyethylene terephthalate (PET) bottle with a tamper resistant child proof closure and two polypropylene measuring syringes: one for small dogs (up to 20 kg) and one for bigger dogs (up to 60 kg).

Not all pack sizes may be marketed.

Disposal

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)

Chanelle Pharmaceuticals Manufacturing Ltd.,

Loughrea,

Co. Galway,

Ireland.

Marketing Authorisation Number

GB:

VM 08749/5010

NI:

EU/2/11/134/001 15 ml

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EU/2/11/134/002 42 ml

EU/2/11/134/003 100 ml

EU/2/11/134/004 200 ml

Significant changes

Date of the first authorisation or date of renewal

09/12/2011

Date of revision of the text

19th October 2021

Any other information

Nil

Legal category

Legal category:POM-V

GTIN

GTIN description:Inflacam 1.5mg/ml Oral Suspension for Dogs 15ml

GTIN:5099299028326

GTIN description:Inflacam 1.5mg/ml Oral Suspension for Dogs 42ml

GTIN:5099299028333

GTIN description:Inflacam 1.5mg/ml Oral Suspension for Dogs 100ml

GTIN:5099299028340