**NOAH Compendium**



Boehringer Ingelheim Animal Health UK Ltd

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**Metacam 1.5 mg/ml oral suspension for dogs**

**Species:**Dogs

**Therapeutic indication:Pharmaceuticals: Neurological preparations:** Analgesics, **Pharmaceuticals: Anti-inflammatory preparations: Oral:** Other NSAIDs, **Pharmaceuticals:** Locomotor (including navicular and osteoarthritis)

**Active ingredient:**Meloxicam

**Product:**Metacam® 1.5 mg/ml oral suspension for dogs

**Product index:**Metacam 1.5 mg/ml oral suspension for dogs

**Incorporating:**

**Presentation**

Each ml contains:

**Active substance:**

Meloxicam: 1.5 mg (equivalent to 0.05 mg per drop)

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is e of the veterinary medicinal product** |
|---|---|
| Sodium benzoate | 1.5 mg (equivalent to 0.05 mg per drop) |
| Sorbitol, liquid | |
| Glycerol | |
| Saccharin sodium | |

**NOAH Compendium**

Xylitol

Sodium dihydrogen phosphate dihydrate

Silica, colloidal anhydrous

Hydroxyethylcellulose

Citric acid

Honey aroma

Water, purified

Yellowish viscous oral suspension with a green tinge.

**Uses**

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

**Dosage and administration**

**Administration routes and dosage**

Oral use.

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 the veterinary medicinal product 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.

To be administered orally either mixed with food or directly into the mouth.

The suspension can be given using either the drop dispenser of the bottle (for very small breeds) or the measuring syringe provided in the package.

<u>Dosing procedure using the drop dispenser of the bottle:</u>

Initial dose: 4 drops /kg body weight

Maintenance dose: 2 drops /kg body weight.

<u>Dosing procedure using the measuring syringe:</u>

The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required. Alternatively therapy may be initiated with Metacam 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.

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. Shake well before use.

Avoid introduction of contamination during use.

**Contra-indications, warnings, etc**

**Contraindications**

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 cases 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**

None.

**Special precautions for use**

Special precautions for safe use in the target species:

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, Metacam 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.

This veterinary medicinal product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

Special precautions for the protection of the environment:

Not applicable.

**Adverse events**

Dogs:

| | |
|---|---|
| Very rare | Appetite loss1, lethargy1 |
| (<1 animal / 10,000 animals treated, including isolated reports): | Vomiting1, diarrhoea1, blood in faeces1,2, haemorrh gastric ulcer, small intestine ulcer1 |
| | Elevated liver enzymes1 |
| | Renal failure1 |

1 These adverse events occur generally within the first treatment week and are in most casestransient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

2 Occult

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.

**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.

**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 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 pharmacological properties of the products used previously.

**Pharmaceutical precautions**

**Major incompatibilities**

None known.

**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.

**Special precautions for storage**

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

**Nature and composition of immediate packaging**

Polyethylene bottle containing 10 ml, 32 ml, 100 ml or 180 ml with a polyethylene dropper and a tamper-proof child-resistant closure. Each bottle is packed in a cardboard box and is equipped with a polypropylene measuring syringe. Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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.

**Legal category**

**Legal category:**POM-V

**Packaging quantities**

Polyethylene bottle containing 10 ml, 32 ml, 100 ml or 180 ml with a polyethylene dropper and a tamper proof child resistant closure. Each bottle is packed in a cardboard box and is equipped with a polypropylene measuring syringe. Not all pack sizes may be marketed.

**Further information**

**PHARMACOLOGICAL INFORMATION**

**ATCvet code:**

QM01AC06

**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).

**Pharmacokinetics**

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. 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.

**DATE OF THE LAST REVISION**

February 2025

**Marketing Authorisation Holder (if different from distributor)**

Boehringer Ingelheim Vetmedica GmbH

55216 Ingelheim am Rhein

Germany

**Marketing Authorisation Number**

UK(GB): Vm 04491/5017

UK(NI): EU/2/97/004/003 : 10 ml

UK(NI): EU/2/97/004/004 : 32 ml

UK(NI): EU/2/97/004/005 : 100 ml

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UK(NI): EU/2/97/004/029 : 180 ml

**Significant changes**

**GTIN**

**GTIN description:**Metacam 1.5 mg/ml Oral Suspension for Dogs - 10ml

**GTIN:**5012917010053

**GTIN description:**Metacam 1.5 mg/ml Oral Suspension for Dogs - 32ml

**GTIN:**5012917010060

**GTIN description:**Metacam 1.5 mg/ml Oral Suspension for Dogs - 100ml

**GTIN:**5012917010077

**GTIN description:**Metacam 1.5 mg/ml Oral Suspension for Dogs - 180ml

**GTIN:**5012917010251