Metacam 1.5 mg/ml oral suspension for dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Neurological preparations: Analgesics, Other NSAIDs, 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

Presentation

Yellowish viscous oral suspension with a green tinge. One ml contains 1.5 mg meloxicam as active substance (equivalent to 0.05 mg per drop) and 1.5 mg sodium benzoate (equivalent to 0.05 mg per drop).

Uses

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

Dosage and administration

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 Metacam 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 either the drop dispenser of the bottle (for very small breeds) or the measuring syringe provided in the package.

Dosing procedure using the drop dispenser of the bottle:

Initial dose: 4 drops /kg body weight

Maintenance dose: 2 drops /kg body weight.

Dosing procedure using the measuring syringe:

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. Avoid introduction of contamination during use.

Contra-indications, warnings, etc

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 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, Metacam 0.5 mg/ml oral suspension for cats should be used.

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.

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

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

In case of overdose, symptomatic treatment should be initiated.

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.

Pharmaceutical precautions

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

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

Keep out of the sight and reach of children. For animal treatment only.

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

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

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. 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.

Marketing Authorisation Holder (if different from distributor)

Boehringer Ingelheim Vetmedica GmbH

55216 Ingelheim am Rhein

Germany

Marketing Authorisation Number

EU/2/97/004/003 : 10 ml

EU/2/97/004/004 : 32 ml

EU/2/97/004/005 : 100 ml

EU/2/97/004/029 : 180 ml

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