Metacam 0.5 mg/ml oral suspension for cats

Introduction

Company name: Boehringer Ingelheim Limited

Address: Ellesfield Avenue

Bracknell

Berkshire RG12 8YS

Telephone: Sales & Marketing Enquiries 01344 746959

Telephone: Technical Enquiries 01344 746957

Fax: 01344 741349

Presentation

Yellowish viscous oral suspension with a green tinge. One ml contains 0.5 mg meloxicam as active ingredient (equivalent to 0.017 mg per drop) and 1.5 mg sodium benzoate (equivalent to 0.05 mg per drop).

Uses

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery. For alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.

Dosage and administration

Post-operative pain and inflammation following surgical procedures:

After initial treatment with Metacam 2 mg/ml solution for injection for cats, continue treatment 24 hours later with Metacam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to four days.

Acute musculo-skeletal disorders:

Initial treatment is a single oral 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 dose of 0.05 mg meloxicam/kg body weight for as long as acute pain and inflammation persist.

Chronic musculo-skeletal disorders:

Initial treatment is a single oral dose of 0.1 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 0.05 mg meloxicam/kg body weight.

A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at

the latest if no clinical improvement is apparent.

Route and method of administration

Dosing procedure using the drop dispenser of the bottle:

Dose of 0.2 mg meloxicam/kg body weight: 12 drops /kg body weight

Dose of 0.1 mg meloxicam/kg body weight: 6 drops /kg body weight

Dose of 0.05 mg meloxicam/kg body weight: 3 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 dose of 0.05 mg meloxicam/kg body weight. Thus for initiation of the treatment of chronic musculo-skeletal disorders on the first day, twice the maintenance volume will be required. For initiation of the treatment of acute musculo-skeletal disorders on the first day, 4 times the maintenance volume will be required.

Shake well before use. To be administered orally either mixed with food or directly into the mouth. The suspension can be given using the drop dispenser of the bottle for cats of any body weight. Alternatively and for cats with a body weight of at least 2 kg, the measuring syringe provided in the package can be used.

Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded.

Avoid introduction of contamination during use.

Contra-indications, warnings, etc

Do not use in pregnant or lactating animals.

Do not use in cats 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 cats 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.

Post-operative pain and inflammation following surgical procedures: In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders: Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

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.

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 elevated liver enzymes have been reported.

These side effects 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, anticoagulant, 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. Concurrent administration of potential nephrotoxic drugs should be avoided.

Pre-treatment with anti-inflammatory substances other than Metacam 2 mg/ml solution for injection for cats at a single dose of 0.2 mg/kg 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.

Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.

In case of overdose, adverse reactions as listed above are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

Pharmaceutical precautions

Shelf-life of the veterinary medicinal product as packaged for sale: 3 ml bottle: 2 years, 10 ml, 15 ml and 30 ml bottle: 3 years.

Shelf-life after first opening the immediate packaging: 3 ml bottle: 14 days, 10 ml, 15 ml and 30 ml bottle: 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

POM-V

Packaging Quantities

Polypropylene bottle containing 3 ml with a polyethylene dropper and a tamper proof child resistant closure. Polyethylene bottle containing 10 ml, 15 ml or 30 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 1 ml polypropylene measuring syringe which has a kg-body weight scale for cats (2 to 10 kg) and a

pictogram showing a cat. 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 properties

Absorption

If the animal is fasted when dosed, the maximal plasma concentrations are obtained after approximately 3 hours. If the animal is fed at the time of dosing, the absorption may be slightly delayed.

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.

Metabolism

Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Five major metabolites were detected all having been shown to be pharmacologically inactive. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. As for other species investigated, the main pathway of meloxicam biotransformation in cat is oxidation.

Elimination

Meloxicam is eliminated with a half-life of 24 hours. The detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21% of the recovered dose is eliminated in urine (2% as unchanged meloxicam, 19% as metabolites) and 79% in the faeces (49% as unchanged meloxicam, 30% as metabolites).

Marketing Authorisation Holder (if different from distributor)

Boehringer Ingelheim Vetmedica GmbH

55216 Ingelheim am Rhein

Germany

Marketing authorisation number

EU/2/97/004/034 – 3 ml.

EU/2/97/004/033 – 10 ml.

EU/2/97/004/026 – 15 ml.

EU/2/97/004/049 – 30 ml.

Significant Changes

GTIN (Global Trade Item No)

Metacam 0.5 mg/ml Oral Suspension for Cats - 3ml

5012917010152

Metacam 0.5 mg/ml Oral Suspension for Cats - 15ml

5012917010176

Metacam 0.5 mg/ml Oral Suspension for Cats - 30ml

5012917010367