

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for cats and guinea pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 0.5 mg (equivalent to 0.017 mg per drop)

Excipient:

Sodium benzoate 1.5 mg (equivalent to 0.05 mg

per drop) For the full list of excipients, see section

6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

Yellowish viscous oral suspension with a green tinge.

4. CLINICAL PARTICULARS

4.1 Target species

Cats and guinea pigs

4.2 Indications for use, specifying the target species

Cats:

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.

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

Guinea pigs:

Alleviation of mild to moderate post-operative pain associated with soft tissue surgery such as male castration.

4.3 Contraindications

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 cases of hypersensitivity to the active substance or to any of the excipients. Do not use in cats less than 6 weeks of age. Do not use in guinea pigs less than 4 weeks of age.

4.4 Special warnings for each target species

None.

4.5 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.

Post-operative use in cats and guinea pigs:

In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders in cats:

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.

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

4.6 Adverse reactions (frequency and seriousness)

In cats, typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have very rarely been reported from post-marketing safety experience. Gastrointestinal ulceration and elevated liver enzymes were reported in very rare cases from post-marketing safety experience.

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 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).

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

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.

In cats, 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.

4.9 Amounts to be administered and

administration route Cats:

Dosage

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.

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.

Guinea pigs:

Dosage

Post-operative pain associated with soft tissue surgery:

Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on day 1 (pre-surgery). Treatment is to be continued once daily by oral administration (at 24-hours intervals) at a dose of 0.1 mg meloxicam/kg body weight on day 2 to day 3 (post-surgery).

The dose can, at the discretion of the veterinarian, be titrated up to 0.5 mg/kg in individual cases. The safety of doses exceeding 0.6 mg/kg has, however, not been evaluated in guinea pigs.

Route and method of administration

The suspension should be given directly into the mouth using a standard 1 ml syringe graduated with ml scale and 0.01 ml increments.

Dose of 0.2 mg meloxicam/kg body weight: 0.4 ml/kg body weight

Dose of 0.1 mg meloxicam/kg body weight: 0.2 ml/kg body weight

Use a small container (e.g. a teaspoon) and drop Metacam oral suspension into the container (it is advised to dispense a few drops more than required into the small container). Use a standard 1 ml syringe to draw up Metacam according to the bodyweight of the guinea pig. Administer Metacam with the syringe directly into the mouth of the guinea pig. Wash the small container with water and dry prior to the next use.

Do not use the cat syringe with the kg-body weight scale and the cat pictogram for guinea pigs.

Advice on correct administration

Shake well before use.

Avoid introduction of contamination during use.

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

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 in section 4.6, are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

In guinea pigs, an overdose of 0.6 mg/kg body weight administered during 3 days followed by a dose of

0.3 mg/kg during 6 additional days did not cause adverse events typical for meloxicam. The safety of doses exceeding 0.6 mg/kg has not been evaluated in guinea pigs.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids (oxicams). ATCvet code: QM01AC06.

5.1 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).

5.2 Pharmacokinetic

particulars Cats:

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).

Guinea pigs:

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate Sorbitol, liquid Glycerol Saccharin sodium Xylitol
Sodium dihydrogen phosphate dihydrate Silica, colloidal anhydrous
Hydroxyethylcellulose
Citric acid Honey aroma Water, purified

6.2 Major incompatibilities

None known.

6.3 Shelf life

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.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials 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.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim
Vetmedica GmbH 55216
Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBERS

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07.01.1998
Date of last renewal: 06.12.2007

10. 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/>.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.