

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 2 mg/ml solution for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 2 mg

Excipients:

Ethanol 150 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for
injection.
Clear yellow
solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

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

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 nor in cats of less than 2 kg.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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

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

During anaesthesia, monitoring and fluid therapy should be considered as standard practice. In case additional pain relief is required, multimodal pain therapy should be considered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals Accidental self-injection may give rise to pain. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

In case of accidental self-injection, 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)

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 adverse reactions are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

Anaphylactoid reactions have been observed very rarely from post-marketing safety experience and should be treated symptomatically.

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, 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. Concurrent administration of potential nephrotoxic veterinary medicinal products should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

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.

4.9 Amounts to be administered and administration route

Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.1 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.

To continue treatment for up to five days, this initial dose may be followed 24 hours later by administration of 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 for up to a total of four doses at 24 hour intervals.

Single subcutaneous injection of 0.3 mg meloxicam/kg body weight (i.e. 0.15 ml/kg body weight) has also been shown to be safe and efficacious for the reduction of post-operative pain and inflammation. This treatment can be considered in cats undergoing surgery where no oral follow-up treatment is possible e.g. feral cats. In this case do not use oral follow up treatment.

Particular care should be taken with regard to the accuracy of dosing. Avoid introduction of contamination during use.

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

In the case of overdose symptomatic treatment should be initiated.

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

Absorption

Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 1.1 µg/ml were reached approximately 1.5 hours post administration.

Distribution

There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.09 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. 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).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Poloxamer 188
Macrogol 300
Glycine
Disodium edetate
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Meglumine
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 28 days.

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

Cardboard box containing one colourless glass injection vial of 10 ml or 20 ml, closed with a rubber stopper and sealed with an aluminium cap. 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/2/97/004/039 10 ml
EU/2/97/004/040 20 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.