

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 5 mg

Excipient:

Ethanol 150 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves and young cattle) and pigs

4.2 Indications for use, specifying the target species

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For the relief of post-operative pain following dehorning in calves.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For the relief of post-operative pain associated with minor soft tissue surgery such as castration.

4.3 Contraindications

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
Do not use in pigs less than 2 days old.

4.4 Special warnings for each target species

Treatment of calves with Metacam 20 minutes before dehorning reduces post-operative pain. Metacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Treatment of piglets with Metacam before castration reduces post-operative pain. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed. To obtain the best possible pain relieving effect post-surgery Metacam should be administered 30 minutes before surgical intervention.

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 very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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.

4.6 Adverse reactions (frequency and seriousness)

Subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Cattle: Can be used during pregnancy.

Pigs: Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

4.9 Amounts to be administered and administration route

Cattle:

Single subcutaneous or intravenous injection at a dose of 0.5 mg meloxicam/kg body weight (i.e. 10.0 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:Locomotor disorders:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.

Reduction of post-operative pain:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.

Avoid introduction of contamination during use.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal periods

Cattle: Meat and offal: 15 days

Pigs: Meat and offal: 5 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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, anti-exudative, analgesic and antipyretic properties. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B₂ induced by *E. coli* endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particularsAbsorption

After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/ml were reached after 7.7 hours in young cattle.

Following single intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.1 to 1.5 µg/ml was reached within 1 hour in pigs.

Distribution

More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism

Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain 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 26 hours after subcutaneous injection in young cattle.

In pigs, after intramuscular administration, the mean plasma elimination half-life is approximately 2.5 hours. Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Poloxamer 188
Sodium chloride
Glycine
Sodium hydroxide
Glycofurol
Meglumine
Water for injections

6.2 Incompatibilities

None known.

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 with 1 or 12 colourless glass injection vial(s) of 20 ml, 50 ml or 100 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/2/97/004/035 1 x 20 ml
EU/2/97/004/037 1 x 50 ml
EU/2/97/004/001 1 x 100 ml
EU/2/97/004/036 12 x 20 ml

EU/2/97/004/038 12 x 50 ml
EU/2/97/004/010 12 x 100 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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 1.5 mg (equivalent to 0.05 mg per drop)

Excipient:

Sodium benzoate 1.5 mg (equivalent to 0.05 mg per drop)

For a 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

Dogs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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.

4.4 Special warnings

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.

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.

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 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 frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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.

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

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.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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

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.

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 Incompatibilities

None known.

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: 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

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.

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/2/97/004/003 10 ml
EU/2/97/004/004 32 ml
EU/2/97/004/005 100 ml
EU/2/97/004/029 180 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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 5 mg

Excipient:

Ethanol 150 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

Dogs:

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

4.3 Contraindications

Do not use in pregnant or lactating animals.

Do not use in animals 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 animals 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

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity. During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

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 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.

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 occasionally been reported. In very rare cases elevated liver enzymes have been reported.

In very rare cases, haemorrhagic diarrhoea, haematemesis and gastrointestinal ulceration 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.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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 displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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 drugs 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

Dogs:

Musculo-skeletal disorders:

Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight). Metacam 1.5 mg/ml oral suspension for dogs or Metacam 1 mg and 2.5 mg chewable tablets for dogs may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight,

24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours):

Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

Cats:

Reduction of post-operative pain:

Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.

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 case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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 0.73 µg/ml in dogs and 1.1 µg/ml in cats were reached approximately 2.5 hours and 1.5 hours post administration, respectively.

Distribution

There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs and cats. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

Metabolism

In dogs, 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.

In cats, 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

In dogs, 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.

In cats, 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
Sodium chloride
Glycine
Sodium hydroxide
Glycofurol
Meglumine
Water for injections

6.2 Incompatibilities

None known.

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/2/97/004/006 10 ml
EU/2/97/004/011 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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 20 mg

Excipient:

Ethanol 150 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pigs and horses

4.2 Indications for use, specifying the target species

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxæmia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

4.3 Contraindications

See also section 4.7.

Do not use in horses less than 6 weeks of age.

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

4.4 Special warnings for each target species

Treatment of calves with Metacam 20 minutes before dehorning reduces post-operative pain. Metacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

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 very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

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.

4.6 Adverse reactions (frequency and seriousness)

In cattle and pigs, subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Cattle and pigs: Can be used during pregnancy and lactation.

Horses: Do not use in pregnant or lactating mares.

See also section 4.3.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

4.9 Amounts to be administered and administration route

Cattle:

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses:

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo-skeletal disorders, Metacam 15 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Avoid introduction of contamination during use.

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

In case of overdose, symptomatic treatment should be initiated.

4.11 Withdrawal periods

Cattle: Meat and offal: 15 days; Milk: 5 days

Pigs: Meat and offal: 5 days

Horses: Meat and offal: 5 days.

Not authorised to use in horses producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B₂ induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

5.2 Pharmacokinetic particulars

Absorption

After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.

After two intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.9 µg/ml was reached after 1 hour in pigs.

Distribution

More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism

Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain 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. The metabolism in horses has not been investigated.

Elimination

Meloxicam is eliminated with a half-life of 26 hours and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively.

In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.

In horses, after intravenous injection meloxicam is eliminated with a terminal half-life of 8.5 hours.

Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale (20 ml, 50 ml, 100 ml or 250 ml vials):
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 with either 1 or 12 colourless glass injection vial(s) each containing 20 ml, 50 ml or 100 ml.

Cardboard box with either 1 or 6 colourless glass injection vial(s) each containing 250 ml.
Each vial is 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/2/97/004/027 1 x 20 ml
EU/2/97/004/007 1 x 50 ml
EU/2/97/004/008 1 x 100 ml
EU/2/97/004/031 1 x 250 ml
EU/2/97/004/028 12 x 20 ml
EU/2/97/004/014 12 x 50 ml
EU/2/97/004/015 12 x 100 ml
EU/2/97/004/032 6 x 250 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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 15 mg/ml oral suspension for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 15 mg

Excipient:

Sodium benzoate 1.5 mg

For a 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

Horses

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in pregnant or lactating mares.

Do not use in horses 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 horses less than 6 weeks of age.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

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

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.

4.6 Adverse reactions (frequency and seriousness)

Isolated cases of adverse reactions typically associated with NSAIDs were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible.

In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

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 displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in cattle have not provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore the use in this species is not recommended during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

4.9 Amounts to be administered and administration route

To be administered either mixed with food or directly into the mouth at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. In case the product is mixed with food, it should be added to a small quantity of food, prior to feeding.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale.

Shake well before use.

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

Avoid introduction of contamination during use.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period

Meat and offal: 3 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B₂ induced by intravenous *E. coli* endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particulars

Absorption

When the product is used according to the recommended dosage regime the oral bioavailability is approximately 98 %. Maximal plasma concentrations are obtained after approximately 2–3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution

Approximately 98 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

Metabolism

The metabolism is qualitatively similar in rats, mini-pigs, humans, cattle and pigs although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy-metabolites and the oxalyl-metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination

Meloxicam is eliminated with a terminal half-life of 7.7 hours.

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 Incompatibilities

None known.

6.3 Shelf life

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

Cardboard box containing one polyethylene bottle of 100 ml or 250 ml with a polyethylene tip adapter and a tamper proof child resistant closure and a measuring syringe. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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/2/97/004/009 100 ml
EU/2/97/004/030 250 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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 0.5 mg (equivalent to 0.02 mg per drop)

Excipients:

Sodium benzoate 1.5 mg (equivalent to 0.06 mg per drop)

For a 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

Dogs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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.

4.4 Special warnings

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.

This product for dogs should not be used in cats due to the different dosing devices. 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.

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 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 frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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.

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

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: 10 drops/kg body weight

Maintenance dose: 5 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.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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

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.

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 Incompatibilities

None known.

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: 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

Polyethylene bottle containing 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 polypropylene measuring syringe.
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/2/97/004/012 15 ml

EU/2/97/004/013 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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1 mg chewable tablets for dogs
Metacam 2.5 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One chewable tablet contains:

Active substance:

Meloxicam 1 mg
Meloxicam 2.5 mg

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablets.

Round mottled beige biconvex tablet, scored on the upper side with embedded code either "M10" or "M25" on one side.

The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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 dogs less than 6 weeks of age or less than 4 kg body weight.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings

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.

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.

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 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 frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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.

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

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day, which can be given orally or alternatively using Metacam 5 mg/ml solution for injection for dogs and cats.

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.

Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively.

Each chewable tablet can be halved for accurate dosing according to the individual body weight of the dog. Metacam chewable tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4.0–7.0	½		0.13–0.1
7.1–10.0	1		0.14–0.1
10.1–15.0	1½		0.15–0.1
15.1–20.0	2		0.13–0.1
20.1–25.0		1	0.12–0.1
25.1–35.0		1½	0.15–0.1
35.1–50.0		2	0.14–0.1

The use of Metacam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of Metacam oral suspension for dogs is recommended.

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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

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 in faeces and the remainder in urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium citrate dihydrate
Starch, pregelatinized
Iron oxide brown
Iron oxide yellow
Cellulose, microcrystalline
Meat Dry Flavour
Silica, colloidal anhydrous
Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf life

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

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 boxes containing 7, 84 or 252 tablets in Alu/Alu child-resistant blisters. 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

Metacam 1 mg chewable tablets for dogs:

Blisters:

EU/2/97/004/043 7 tablets

EU/2/97/004/044 84 tablets

EU/2/97/004/045 252 tablets

Metacam 2.5 mg chewable tablets for dogs:

Blisters:

EU/2/97/004/046 7 tablets

EU/2/97/004/047 84 tablets

EU/2/97/004/048 252 tablets

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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for cats

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 a 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

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.

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

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 case of hypersensitivity to the active substance or to any of the excipients.

Do not use in cats less than 6 weeks of age.

4.4 Special warnings

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 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.

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 occasionally been reported and in very rare cases gastrointestinal ulceration and elevated liver enzymes.

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 displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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.

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

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.

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.

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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

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).

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 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.

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 a 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 case 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

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.

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 occasionally been reported and in very rare cases gastrointestinal ulceration and elevated liver enzymes.

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.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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: Antiinflammatory 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 of 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 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: 2 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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 15 mg/ml oral suspension for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance(s):

Meloxicam 15 mg

Excipient(s):

Sodium benzoate 1.5 mg

For a 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

Pigs

4.2 Indications for use, specifying the target species

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation. For adjunctive therapy in the treatment of puerperal septicaemia and toxæmia (Mastitis-Metritis-Agalactia syndrome MMA) with appropriate antibiotic therapy.

4.3 Contraindications

Do not use in pigs suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings

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 very severely dehydrated, hypovolaemic or hypotensive pigs which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

4.9 Amounts to be administered and administration route

Oral suspension to be administered at a dosage of 0.4 mg/kg body weight (i.e. 2.7 ml/100 kg) in combination with antibiotic therapy, as appropriate. If required, a second administration of Meloxicam can be given after 24 hours.

In cases of MMA with severely disturbed general demeanour (e.g. anorexia) the use of Metacam 20 mg/ml solution for injection is recommended.

To be administered preferably mixed with a small quantity of feed. Alternatively to be given prior to feeding, or directly into the mouth.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale.

Shake well before use.

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period

Meat and offal: 5 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory 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. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B₂ induced by intravenous *E. coli* endotoxin administration in pigs.

5.2 Pharmacokinetic particulars

Absorption

After a single oral dose of 0.4 mg meloxicam/kg a C_{max} value of 0.81 µg/ml was reached after 2 hours.

Distribution

More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism

Meloxicam is predominantly found in plasma. Bile and urine contain 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

After oral administration the mean plasma elimination half-life is approximately 2.3 hours. Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

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 Incompatibilities

None known.

6.3 Shelf life

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

Shelf-life after first opening of the immediate packaging: 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

Cardboard box containing one polyethylene bottle of 100 ml or 250 ml with a polyethylene tip adapter, a tamper proof child resistant closure and a measuring syringe. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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/2/97/004/041 100 ml
EU/2/97/004/042 250 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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml solution for injection for cattle and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:

Meloxicam 40 mg

Excipient:

Ethanol 96 % 156.25 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

Cattle and horses.

4.2 Indications for use, specifying the target species

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Horses:

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

4.3 Contraindications

Do not use in pregnant or lactating mares (see section 4.7).
Do not use in horses less than 6 weeks of age.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

4.4 Special warnings for each target species

Treatment of calves with Metacam 20 minutes before dehorning reduces post-operative pain. Metacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

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 very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

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.

In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofoetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

4.6 Adverse reactions (frequency and seriousness)

In cattle, a slight transient painless swelling at the injection site was observed in most animals in laboratory studies. This local reaction resolved within 8 hours following subcutaneous administration.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Cattle: Can be used during pregnancy and lactation.

Horses: Do not use in pregnant or lactating mares (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anticoagulant agents.

4.9 Amounts to be administered and administration route

Cattle:

Single subcutaneous or intravenous injection at a dose of 0.5 mg meloxicam/kg body weight (i.e. 1.25 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Horses:

Single intravenous injection at a dose of 0.6 mg meloxicam/kg body weight (i.e. 1.5 ml/100 kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo-skeletal disorders, Metacam 15 mg/ml oral suspension may be used for continuation of treatment at a dose of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Avoid introduction of contamination during use.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Cattle: Meat and offal: 15 days; milk: 5 days.

Horses: Meat and offal: 5 days.

Not authorised for use in horses producing milk for human consumption.

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, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B₂ induced by *E. coli* endotoxin administration in calves and lactating cows.

5.2 Pharmacokinetic particulars

Absorption

After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/ml and 2.7 µg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.

Distribution

More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism

Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile 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. The metabolism in horses has not been investigated.

Elimination

Meloxicam is eliminated with a half-life of 26 hours and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively.

In horses, after intravenous injection meloxicam is eliminated with a terminal half-life of 8.5 hours. Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96 %
Poloxamer 188
Macrogol 300
Glycine
Disodium edetate
Sodium hydroxide
Hydrochloric acid
Meglumine
Water for injections

6.2 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

Pack sizes of 1 or 12 colourless glass injection vial(s) each containing 50 ml or 100 ml.
Each vial is 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 NUMBER(S)

EU/2/97/004/050-053

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.

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

Metacam 5 mg/ml solution for injection for cattle and pigs

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
Spain

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Meloxicam in Metacam 5 mg/ml solution for injection for cattle and pigs is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmaco- logically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, <i>Equidae</i>	20_μg/kg 65_μg/kg 65_μg/kg	Muscle Liver Kidney	No entry	Anti-inflammatory agents/Non- steroidal anti- inflammatory agents
		Bovine, caprine	15_μg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

Metacam 1.5 mg/ml oral suspension for dogs

A. MANUFACTURER ING RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

Metacam 5 mg/ml solution for injection for dogs and cats

A. MANUFACTURERS ING RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Labiana Life Sciences S.A
Venus, 26
Can Parellada Industrial
08228 Terrassa
SPAIN

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

Metacam 20 mg/ml solution for injection for cattle, pigs and horses

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
SPAIN

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Meloxicam in Metacam_20 mg/ml solution for injection for cattle, pigs and horses is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, <i>Equidae</i>	20_µg/kg 65_µg/kg 65_µg/kg	Muscle Liver Kidney	No entry	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents
		Bovine, caprine	15_µg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

Metacam 15 mg/ml oral suspension for horses

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Meloxicam in Metacam 15 mg/ml oral suspension for horses is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, <i>Equidae</i>	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	No entry	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents
		Bovine, caprine	15 µg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

Metacam 0.5 mg/ml oral suspension for dogs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

Metacam 1 mg chewable tablets for dogs
Metacam 2.5 mg chewable tablets for dogs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

Metacam 0.5 mg/ml oral suspension for cats

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

Metacam 2 mg/ml solution for injection for cats

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Labiana Life Sciences S.A.

Venus, 26

Can Parellada Industrial

08228 Terrassa

SPAIN

KVP PHARMA + VETERINÄR PRODUKTE GMBH

Projensdorfer Str. 324

24106 Kiel

GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

Metacam 15 mg/ml oral suspension for pigs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Meloxicam in Metacam 15 mg/ml oral suspension for pigs is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, <i>Equidae</i>	20 µg/kg 65 µg/kg 65 µg/kg	Muscle Liver Kidney	No entry	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents
		Bovine, caprine	15 µg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this product.

Metacam 40 mg/ml solution for injection for cattle and horses

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Manufacturers responsible for batch release

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
SPAIN

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in Metacam is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Meloxicam	Meloxicam	Bovine, caprine, porcine, rabbit, Equidae	20_μg/kg 65_μg/kg 65_μg/kg	Muscle Liver Kidney	NO ENTRY	Anti-inflammatory agents/Non-steroidal anti-inflammatory agents
		Bovine, caprine	15_μg/kg	Milk		

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for cattle and pigs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 20 ml
1 x 50 ml
1 x 100 ml
12 x 20 ml
12 x 50 ml
12 x 100 ml

5. TARGET SPECIES

Cattle (calves and young cattle) and pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Single subcutaneous or intravenous injection.

Pigs: Single intramuscular injection. If required, a second administration can be given after 24 hours.

Single intramuscular injection before surgery.

Take care of accurate dosing, use of appropriate dosing device and estimation of body weight.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days

Pigs: meat and offal: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf-life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/035 1 x 20 ml
EU/2/97/004/037 1 x 50 ml
EU/2/97/004/001 1 x 100 ml
EU/2/97/004/036 12 x 20 ml
EU/2/97/004/038 12 x 50 ml
EU/2/97/004/010 12 x 100 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for cattle and pigs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 5 mg/ml

3. PHARMACEUTICAL FORM

solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle (calves and young cattle) and pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV injection.

Pigs: IM injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days

Pigs: meat and offal: 5 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { month/year }
Shelf-life of broached vial: 28 days.
Once broached, use by...

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Read the package leaflet before use.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/001 1 x 100 ml
EU/2/97/004/010 12 x 100 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for cattle and pigs
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV
Pigs: IM

5. WITHDRAWAL PERIOD

Withdrawal period:
Cattle: meat and offal: 15 days
Pigs: meat and offal: 5 days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life of broached vial: 28 days.
Once broached, use by....

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml oral suspension for dogs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 1.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZES

10 ml
32 ml
100 ml
180 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Oral use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}

Shelf-life of opened bottle: 6 months.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

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

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml oral suspension for dogs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 1.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZES

100 ml
180 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { month/year }
Shelf-life of opened bottle: 6 months.
Once broached, use by

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Read the package leaflet before use.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/005 100 ml
EU/2/97/004/029 180 ml

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml oral suspension for dogs
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

3. CONTENT BY WEIGHT; BY VOLUME OR BY NUMBER OF DOSES

10 ml
32 ml

4. ROUTE(S) OF ADMINISTRATION

Shake well before use.
Oral use

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life of opened bottle: 6 months.
Once broached, use by...

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for dogs and cats
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs: Musculo-skeletal disorders: single subcutaneous injection.
Post-operative pain: single intravenous or subcutaneous injection.
Cats: Post-operative pain: single subcutaneous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP. {month/year}

Shelf-life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/006 10 ml

EU/2/97/004/011 20 ml

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for dogs and cats
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

Dogs: IV or SC
Cats: SC

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 20 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE(S)

1 x 20 ml
1 x 50 ml
1 x 100 ml
1 x 250 ml
12 x 20 ml
12 x 50 ml
12 x 100 ml
6 x 250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Single S.C. or I.V. injection.

Pigs: Single I.M. injection. If required, a second administration can be given after 24 hours.

Horses: Single I.V. injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days; milk: 5 days

Pigs: meat and offal: 5 days

Horses: meat and offal: 5 days.

Not authorised to use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { month/year }

Shelf-life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/027 1 x 20 ml
EU/2/97/004/007 1 x 50 ml
EU/2/97/004/008 1 x 100 ml
EU/2/97/004/031 1 x 250 ml
EU/2/97/004/028 12 x 20 ml
EU/2/97/004/014 12 x 50 ml
EU/2/97/004/015 12 x 100 ml

EU/2/97/004/032 6 x 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 20 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE(S)

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV injection.
Pigs: IM injection.
Horses: IV injection.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days; milk: 5 days

Pigs: meat and offal: 5 days

Horses: meat and offal: 5 days.

Not authorised to use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { month/year }
Shelf-life of broached vial: 28 days.
Once broached, use by ...

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Read the package leaflet before use.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/007 1 x 50 ml
EU/2/97/004/008 1 x 100 ml
EU/2/97/004/031 1 x 250 ml
EU/2/97/004/014 12 x 50 ml
EU/2/97/004/015 12 x 100 ml
EU/2/97/004/032 6 x 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV
Pigs: IM
Horses: IV

5. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days; milk: 5 days

Pigs: meat and offal: 5 days

Horses: meat and offal: 5 days.

Not authorised to use in horses producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Shelf-life of broached vial: 28 days.

Once broached, use by...

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 15 mg/ml oral suspension for horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 15 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.

To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth. After administration of the drug, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating mares.

10. EXPIRY DATE

EXP. {month/year}
Shelf-life of opened bottle: 6 months.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/009 100 ml
EU/2/97/004/030 250 ml

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 15 mg/ml oral suspension for horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 15 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { month/year }
Shelf-life of opened bottle: 6 months.
Once broached, use by.....

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Read the package leaflet before use.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/009 100 ml
EU/2/97/004/030 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for dogs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 0.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZES

15 ml
30 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP { month/year }

Shelf-life of opened bottle: 6 months.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/012 15 ml

EU/2/97/004/013 30 ml

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for dogs
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

3. CONTENTS BY WEIGHT; BY VOLUME OR BY NUMBER OF DOSES

15 ml
30 ml

4. ROUTE(S) OF ADMINISTRATION

Shake well before use.
Oral use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life of opened bottle: 6 months.
Once broached, use by...

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box of blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1 mg chewable tablets for dogs
Metacam 2.5 mg chewable tablets for dogs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 1 mg/chewable tablet
Meloxicam 2.5 mg/chewable tablet

3. PHARMACEUTICAL FORM

Chewable tablets

4. PACKAGE SIZE(S)

7 tablets
84 tablets
252 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Metacam 1 mg chewable tablets for dogs:

Oral use.

Single dose on the first day: 0.2 mg meloxicam/kg body weight. Maintenance dose: 0.1 mg meloxicam/kg body weight once daily (1 chewable tablet per 10 kg body weight).

Metacam 2.5 mg chewable tablets for dogs:

Oral use.

Single dose on the first day: 0.2 mg meloxicam/kg body weight. Maintenance dose: 0.1 mg meloxicam/kg body weight once daily (1 chewable tablet per 25 kg body weight).

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { month/year }

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

Metacam 1 mg chewable tablets for dogs:

EU/2/97/004/043 7 tablets

EU/2/97/004/044 84 tablets

EU/2/97/004/045 252 tablets

Metacam 2,5 mg chewable tablets for dogs:

EU/2/97/004/046 7 tablets

EU/2/97/004/047 84 tablets
EU/2/97/004/048 252 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1 mg chewable tablets for dogs
Metacam 2.5 mg chewable tablets for dogs

Meloxicam

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for cats
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 0.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZES

3 ml
10 ml
15 ml
30 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

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.

10. EXPIRY DATE

EXP {month/year}

3 ml:	Shelf-life of opened bottle:	14 days
10 ml:	Shelf-life of opened bottle:	6 months.
15 ml:	Shelf-life of opened bottle:	6 months.
30 ml:	Shelf-life of opened bottle:	6 months.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. 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

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for cats
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

3. CONTENTS BY WEIGHT; BY VOLUME OR BY NUMBER OF DOSES

3 ml

4. ROUTE OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life of opened bottle: 14 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for cats
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

3. CONTENTS BY WEIGHT; BY VOLUME OR BY NUMBER OF DOSES

10 ml
15 ml
30 ml

4. ROUTE OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life of opened bottle: 6 months.
Once broached, use by...

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 2 mg/ml solution for injection for cats
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 2 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml
20 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single subcutaneous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.
Read the package leaflet before use.

10. EXPIRY DATE

EXP. {month/year}

Shelf-life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Not applicable.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/039 10 ml

EU/2/97/004/040 20 ml

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 2 mg/ml solution for injection for cats
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 2 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
20 ml

4. ROUTE OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life of broached vial: 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 15 mg/ml oral suspension for pigs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 15 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.
Preferably mixed with small quantity of feed. Alternatively, prior to feeding or directly into the mouth.
After use, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP. {month/year}

Shelf-life of opened bottle: 6 months.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/041 100 ml

EU/2/97/004/042 250 ml

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 15 mg/ml oral suspension for pigs
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 15 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.

After use, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Meat and offal: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life of opened bottle: 6 months.
Once broached, use by.....

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Read the package leaflet before use.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/041 100 ml
EU/2/97/004/042 250 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 50 ml and 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml solution for injection for cattle and horses
meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZES

50 ml
100 ml
12 x 50 ml
12 x 100 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: subcutaneous use, intravenous use.
Horses: Intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days; milk: 5 days.

Horses: meat and offal: 5 days.

Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP { month/year }
Once broached use within 28 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/97/004/050 50 ml
EU/2/97/004/051 100 ml
EU/2/97/004/052 12 x 50 ml
EU/2/97/004/053 12 x 100 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial, 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml solution for injection for cattle and horses
meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE(S)

100 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: SC, IV

Horses: IV

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days; milk: 5 days.

Horses: meat and offal: 5 days.

Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached, use by...

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/051 100 ml.
EU/2/97/004/053 12 x 100 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml injection for cattle and horses
meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 40 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC, IV
Horses: IV

5. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days; milk: 5 days.

Horses: meat and offal: 5 days.

Not authorised for use in horses producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Once broached, use by...

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

**PACKAGE LEAFLET FOR:
Metacam 5 mg/ml solution for injection for cattle and pigs**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for batch release

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
SPAIN

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for cattle and pigs
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:

Meloxicam	5 mg
Ethanol	150 mg.

4. INDICATION(S)

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For the relief of post-operative pain following dehorning in calves.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For the relief of post operative pain associated with minor soft tissue surgery such as castration.

5. CONTRAINDICATIONS

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
Do not use in pigs less than 2 days old.

6. ADVERSE REACTIONS

Subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (calves and young cattle) and pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle:

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10.0 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Locomotor disorders:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.

Reduction of post-operative pain:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD

Cattle: meat and offal: 15 days

Pigs: meat and offal: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf-life after first opening the container: 28 days.

Do not use after the expiry date stated on the carton and bottle after EXP.

12. SPECIAL WARNING(S)

Treatment of calves with Metacam 20 minutes before dehorning reduces post-operative pain. Metacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Treatment of piglets with Metacam before castration reduces post-operative pain. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed.

To obtain the best possible pain relieving effect post-surgery Metacam should be administered 30 minutes before surgical intervention.

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 very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

Precautions to be taken by the person administering the product

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 this package leaflet or the label to the physician.

Use during pregnancy and lactation

Cattle: Can be used during pregnancy.

Pigs: Can be used during pregnancy and lactation.

Interaction:

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Overdose:

In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

Cardboard box with 1 or 12 colourless glass injection vial(s) of 20 ml, 50 ml or 100 ml.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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**PACKAGE LEAFLET FOR:
Metacam 1.5 mg/ml oral suspension for dogs**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml oral suspension for dogs
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:
Meloxicam 1.5 mg (equivalent to 0.05 mg per drop).

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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.

6. ADVERSE REACTIONS

Typical adverse reactions of Non-Steroidal Anti-Inflammatory Drugs (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 frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)

- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage

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.

Method and route of administration

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.



Shake bottle well.
Push down and unscrew bottle top. Attach the dosing syringe to the drop dispenser of the bottle by gently pushing.

Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to your dog's body weight in kilograms.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.

By pushing the plunger in empty the contents of the syringe onto the food or directly into the mouth.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing.
Please carefully follow the instructions of the veterinarian.
Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf-life after first opening the container: 6 months.
Do not use after the expiry date stated on the carton and the bottle after EXP.

12. SPECIAL WARNING(S)

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.

Precautions to be taken by the person administering the product

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Use during pregnancy and lactation

See section "Contraindications".

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.

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.

Overdose:

In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

10 ml, 32 ml, 100 ml or 180 ml bottle. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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**PACKAGE LEAFLET FOR:
Metacam 5 mg/ml solution for injection for dogs and cats**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturers responsible for batch release

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
SPAIN

KVP Pharma + Veterinär Produkte GmbH

Projensdorfer Str. 324
24106 Kiel
GERMANY
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for dogs and cats
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:

Meloxicam	5 mg
Ethanol	150 mg.

4. INDICATION(S)

Dogs:

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.

Do not use in animals 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 animals less than 6 weeks of age nor in cats of less than 2 kg.

6. ADVERSE REACTIONS

Typical adverse reactions of Non-Steroidal Anti-Inflammatory Drugs (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.

In very rare cases, haemorrhagic diarrhoea, haematemesis and gastrointestinal ulceration 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.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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 displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage for each species

Dogs: single administration of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg).

Cats: single administration of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg).

Method and routes of administration

Dogs:

Musculo-skeletal disorders: single subcutaneous injection.

Metacam 1.5 mg/ml oral suspension for dogs or Metacam 1 mg and 2.5 mg chewable tablets for dogs may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours): single intravenous or subcutaneous injection before surgery, for example at the time of induction of anaesthesia.

Cats:

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery: single subcutaneous injection before surgery, for example at the time of induction of anaesthesia.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf-life after first opening the container: 28 days.
Do not use after the expiry date stated on the carton and the bottle after EXP.

12. SPECIAL WARNING(S)

Precautions for use in animals

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity. During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

Precautions to be taken by the person administering the product

Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician.

Use during pregnancy and lactation

See section "Contraindications".

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 drugs 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.

Overdose:

In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

10 ml or 20 ml injection vial. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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PACKAGE LEAFLET FOR:
Metacam 20 mg/ml solution for injection for cattle, pigs and horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturers responsible for batch release

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
SPAIN

KVP Pharma + Veterinär Produkte GmbH

Projensdorfer Str. 324
24106 Kiel
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:

Meloxicam	20 mg
Ethanol	150 mg.

4. INDICATION(S)

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs:

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxæmia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

5. CONTRAINDICATIONS

Do not use in horses less than 6 weeks of age.

Do not use in pregnant or lactating mares.

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

6. ADVERSE REACTIONS

In cattle and pigs, subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs and horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle:

Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses:

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo-skeletal disorders, Metacam 15 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIODS

Cattle: meat and offal: 15 days; milk: 5 days

Pigs: meat and offal: 5 days

Horses: meat and offal: 5 days.

Not authorised to use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf-life after first opening the container: 28 days.

Do not use after the expiry date stated on the carton and vial after EXP.

12. SPECIAL WARNING(S)

Treatment of calves with Metacam 20 minutes before dehorning reduces post-operative pain. Metacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

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 very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

Precautions to be taken by the person administering the product

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 this package leaflet or the label to the physician.

Use during pregnancy and lactation

Cattle and pigs: Can be used during pregnancy and lactation.

Horses: Do not use in pregnant or lactating mares.

Interaction:

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Overdose:

In case of overdose, symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

Cardboard box with either 1 or 12 colourless glass injection vial(s) of 20 ml, 50 ml or 100 ml.

Cardboard box with either 1 or 6 colourless glass injection vial(s) of 250 ml.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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**PACKAGE LEAFLET FOR:
Metacam 15 mg/ml oral suspension for horses**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 15 mg/ml oral suspension for horses
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:
Meloxicam 15 mg.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in pregnant or lactating mares.
Do not use in horses 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 horses less than 6 weeks of age.

6. ADVERSE REACTIONS

Isolated cases of adverse reactions typically associated with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) were observed in clinical trials (slight urticaria, diarrhoea). Symptoms were reversible. In very rare cases loss of appetite, lethargy, abdominal pain and colitis have been reported. In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

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 displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)

- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage

Oral suspension to be administered at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days.

Method and route of administration

Shake well before use. To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale.

After administration of the drug, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD

Meat and offal: 3 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf-life after first opening of the container: 6 months.

Do not use after the expiry date stated on the carton and the bottle after EXP.

12. SPECIAL WARNING(S)

Precautions for use in animals

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

Precautions to be taken by the person administering the product

People with known hypersensitivity to 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.

Use during pregnancy and lactation

See section "Contraindications".

Interaction:

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Overdose:

In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

100 ml or 250 ml bottle. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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**PACKAGE LEAFLET FOR:
Metacam 0.5 mg/ml oral suspension for dogs**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for dogs
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:
Meloxicam 0.5 mg (equivalent to 0.02 mg per drop)

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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.

6. ADVERSE REACTIONS

Typical adverse reactions of Non-Steroidal Anti-Inflammatory Drugs (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 frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)

- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage

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.

Method and route of administration

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: 10 drops/kg body weight

Maintenance dose: 5 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.



Shake bottle well.
Push down and unscrew bottle top. Attach the dosing syringe to the drop dispenser of the bottle by gently pushing.

Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to your dog's body weight in kilograms.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.

By pushing the plunger in empty the contents of the syringe onto the food or directly into the mouth.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf-life after first opening the container: 6 months.

Do not use after the expiry date stated on the carton and the bottle after EXP.

12. SPECIAL WARNING(S)

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 due to the different dosing devices. In cats, Metacam 0.5 mg/ml oral suspension for cats should be used.

Precautions to be taken by the person administering the product

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Use during pregnancy and lactation

See section "Contraindications".

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.

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.

Overdose:

In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste

but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

15 ml or 30 ml bottle. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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PACKAGE LEAFLET FOR:
Metacam 1 mg chewable tablets for dogs
Metacam 2.5 mg chewable tablets for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1 mg chewable tablets for dogs
Metacam 2.5 mg chewable tablets for dogs
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One tablet contains:

Meloxicam	1 mg
Meloxicam	2.5 mg.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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 dogs less than 6 weeks of age or less than 4 kg body weight.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Typical adverse reactions of Non-Steroidal Anti-Inflammatory Drugs (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 frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day, which can be given orally or alternatively using Metacam 5 mg/ml solution for injection for dogs and cats.

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.

Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively.

Each chewable tablet can be halved for accurate dosing according to the individual body weight of the dog. Metacam chewable tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4.0–7.0	½		0.13–0.1
7.1–10.0	1		0.14–0.1
10.1– 15.0	1½		0.15–0.1
15.1–20.0	2		0.13–0.1
20.1–25.0		1	0.12–0.1
25.1–35.0		1½	0.15–0.1
35.1–50.0		2	0.14–0.1

The use of Metacam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of Metacam oral suspension for dogs is recommended.

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

Instructions for opening the child-resistant blisters:

Push the tablet for release from the blister.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use after the expiry date stated on the carton and the blister after EXP.

12. SPECIAL WARNING(S)

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.

Precautions to be taken by the person administering the product

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the carton to the physician.

Use during pregnancy and lactation

See section "Contraindications".

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.

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.

Overdose:

In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

Package sizes:

Metacam 1 mg chewable tablets for dogs
Blisters: 7, 84 or 252 tablets.

Metacam 2.5 mg chewable tablets for dogs
Blisters: 7, 84 or 252 tablets.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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**PACKAGE LEAFLET FOR:
Metacam 0.5 mg/ml oral suspension for cats**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for cats
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:
Meloxicam 0.5 mg (equivalent to 0.017 mg per drop).

4. INDICATION(S)

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.

5. 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 case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks of age.

6. ADVERSE REACTIONS

Typical adverse reactions of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported and in very rare cases gastrointestinal ulceration and elevated liver enzymes.

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 displaying adverse reactions during the course of one treatment)

- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 4 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

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.

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.

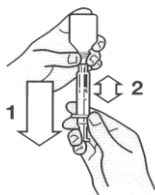
Dosing procedure using the measuring syringe:

The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the dose of 0.05 mg meloxicam/kg bodyweight. Thus for initiation of the treatment of chronic musculo-skeletal disorders on the first day, twice the maintenance volume will be required.

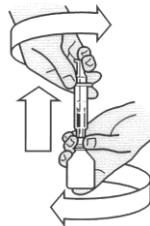
For initiation of the treatment of acute musculo-skeletal disorders on the first day, 4 times the maintenance volume will be required.



Shake bottle well.
Push down and unscrew bottle top. Attach the dosing syringe to the drop dispenser of the bottle by gently pushing.



Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to your cat's body weight in kilograms.



Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.



By pushing the plunger in empty the contents of the syringe onto the food or directly into the mouth.

9. ADVICE ON CORRECT ADMINISTRATION

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

Please carefully follow the instructions of the veterinarian.

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf-life after first opening the container:

3 ml bottle: 14 days
10 ml, 15 ml and 30 ml bottles: 6 months.

Do not use after the expiry date stated on the carton and the bottle after EXP.

12. SPECIAL WARNING(S)

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.

Precautions to be taken by the person administering the product

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Use during pregnancy and lactation

See section "Contraindications".

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 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.

Overdose:

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 "Adverse reactions", are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

3 ml, 10 ml, 15 ml or 30 ml bottle. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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**PACKAGE LEAFLET FOR:
Metacam 2 mg/ml solution for injection for cats**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturers responsible for batch release

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
SPAIN

KVP Pharma + Veterinär Produkte GmbH

Projensdorfer Str. 324
24106 Kiel
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 2 mg/ml solution for injection for cats
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:

Meloxicam	2 mg
Ethanol	150 mg.

4. INDICATION(S)

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

5. 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 case 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.

6. ADVERSE REACTIONS

Typical adverse reactions of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as loss of appetite,

vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported and in very rare cases gastrointestinal ulceration and elevated liver enzymes.

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.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Single subcutaneous injection 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf-life after first opening the container: 28 days.

Do not use after the expiry date stated on the carton and the vial after EXP.

12. SPECIAL WARNING(S)

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.

Precautions to be taken by the person administering the product

Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.

In case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician.

Use during pregnancy and lactation

See section "Contraindications".

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.

Overdose:

In the case of overdose symptomatic treatment should be initiated.

Incompatibilities

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

10 ml or 20 ml injection vial. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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**PACKAGE LEAFLET FOR:
Metacam 15 mg/ml oral suspension for pigs**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 15 mg/ml oral suspension for pigs
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One ml contains:
Meloxicam 15 mg.

4. INDICATION(S)

For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.

For adjunctive therapy in the treatment of puerperal septicaemia and toxemia (Mastitis-Metritis-Agalactia syndrome MMA) with appropriate antibiotic therapy.

5. CONTRAINDICATIONS

Do not use in pigs suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

None.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral suspension to be administered at a dosage of 0.4 mg/kg body weight (i.e. 2.7 ml/100 kg) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

In cases of MMA with severely disturbed general demeanour (e.g. anorexia) the use of Metacam 20 mg/ml solution for injection is recommended.

Shake well before use.

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

9. ADVICE ON CORRECT ADMINISTRATION

To be administered preferably mixed with a small quantity of feed. Alternatively to be given prior to feeding, or directly into the mouth.

The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale.

10. WITHDRAWAL PERIOD

Meat and offal: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf-life after first opening of the container: 6 months.

Do not use after the expiry date stated on the carton and the bottle after EXP.

12. SPECIAL WARNING(S)

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 very severely dehydrated, hypovolaemic or hypotensive pigs which require parenteral rehydration, as there may be a potential risk of renal toxicity.

Precautions to be taken by the person administering the product

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.

Use during pregnancy and lactation

Can be used during pregnancy and lactation.

Interaction:

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Overdose:

In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

100 ml or 250 ml bottle. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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PACKAGE LEAFLET FOR:
Metacam 40 mg/ml solution for injection for cattle and horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturers responsible for batch release

Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml solution for injection for cattle and horses
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One ml contains:

Active substance:

Meloxicam	40 mg
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Excipient:

Ethanol 96 %	156.25 mg.
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Clear yellow solution.

4. INDICATION(S)

Cattle:

For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.

For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.

For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.

For the relief of post-operative pain following dehorning in calves.

Horses:

For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.

For the relief of pain associated with equine colic.

5. CONTRAINDICATIONS

Do not use in horses less than 6 weeks of age.

Do not use in pregnant or lactating mares (see section “Pregnancy and lactation”).
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

6. ADVERSE REACTIONS

In cattle a slight transient painless swelling at the injection site was observed in most animals in laboratory studies. This local reaction resolved within 8 hours following subcutaneous administration.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

In very rare cases anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle:

Single subcutaneous or intravenous injection at a dose of 0.5 mg meloxicam/kg body weight (i.e. 1.25 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Horses:

Single intravenous injection at a dose of 0.6 mg meloxicam/kg body weight (i.e. 1.5 ml/100 kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo-skeletal disorders, Metacam 15 mg/ml oral suspension may be used for continuation of treatment at a dose of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD

Cattle: meat and offal: 15 days; milk: 5 days.

Horses: meat and offal: 5 days.

Not authorised for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Treatment of calves with Metacam 20 minutes before dehorning reduces post-operative pain. Metacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

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 very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

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.

In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

Pregnancy and lactation:

Cattle: Can be used during pregnancy and lactation.

Horses: Do not use in pregnant or lactating mares (see section "Contraindications").

Interaction with other medicinal products and other forms of interaction:

Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anticoagulant agents.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose, symptomatic treatment should be initiated.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

Pack sizes of 1 or 12 colourless glass injection vial(s) of 50 ml or 100 ml.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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