

Metacam™ 20 mg/ml Solution for Injection for Cattle and Pigs

Presentation

Each ml of the solution for injection contains 20 mg meloxicam and 150 mg ethanol (as preservative).

Uses

Metacam 20 mg/ml solution is a non-steroidal anti-inflammatory drug (NSAID) for use in cattle and pigs.

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 rehydration 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.

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.

Dosage and administration

Cattle: Single subcutaneous or intravenous injection at a dose rate of 0.5mg meloxicam/kg bodyweight (i.e. 2.5 ml/100 kg bodyweight) in combination with antibiotic therapy or with oral rehydration therapy as appropriate.

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

WITHDRAWAL PERIOD START

Withdrawal Period Information - PLEASE DO NOT REMOVE

<i>Include in WP Book (yes/no)</i>	<i>Changed since last WP Book (yes/no)</i>	<i>Cattle Milk</i>	<i>Cattle Meat</i>	<i>Sheep Meat</i>	<i>Pig Meat</i>	<i>Poultry Meat</i>	<i>Poultry Eggs</i>	<i>Fish Meat</i>	<i>Notes</i>
Yes	No	5 days	15 days	-	5 Days	-	-	-	

WITHDRAWAL PERIOD END

Contra-indications, warnings, etc

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastro-intestinal lesions or individual hypersensitivity to the product.

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

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

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

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 case of overdosage, symptomatic treatment should be initiated.

Operator warnings

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 insert or label to the physician.

Disposal Advice

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

For animal treatment only.

Keep out of reach of children.

Withdrawal Period

Cattle:

Meat and offal – 15 days.

Milk – 5 days.

Pigs:

Meat and offal – 5 days.

Pharmaceutical precautions

Shelf life of broached vial: 28 days

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

Avoid introduction of contamination during use.

Legal category

POM

Package quantities

Colourless glass injection vials of 50 ml, sealed with a rubber stopper and aluminium cap.

Further information

Pharmacodynamic properties

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, 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, lactating cows and pigs.

Pharmacokinetic properties:

Absorption

After a single subcutaneous dose of 0.5mg meloxicam/kg, C_{max} values of 2.1µg/ml and 2.7µg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively. After two intramuscular doses of 0.4mg 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 predominately found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile where as 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 and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively. In pigs, after intramuscular injection, 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.

Marketing authorisation number

50 ml EU/2/97/004/007

Marketing Authorisation Holder:

Boehringer Ingelheim Vetmedica GmbH

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