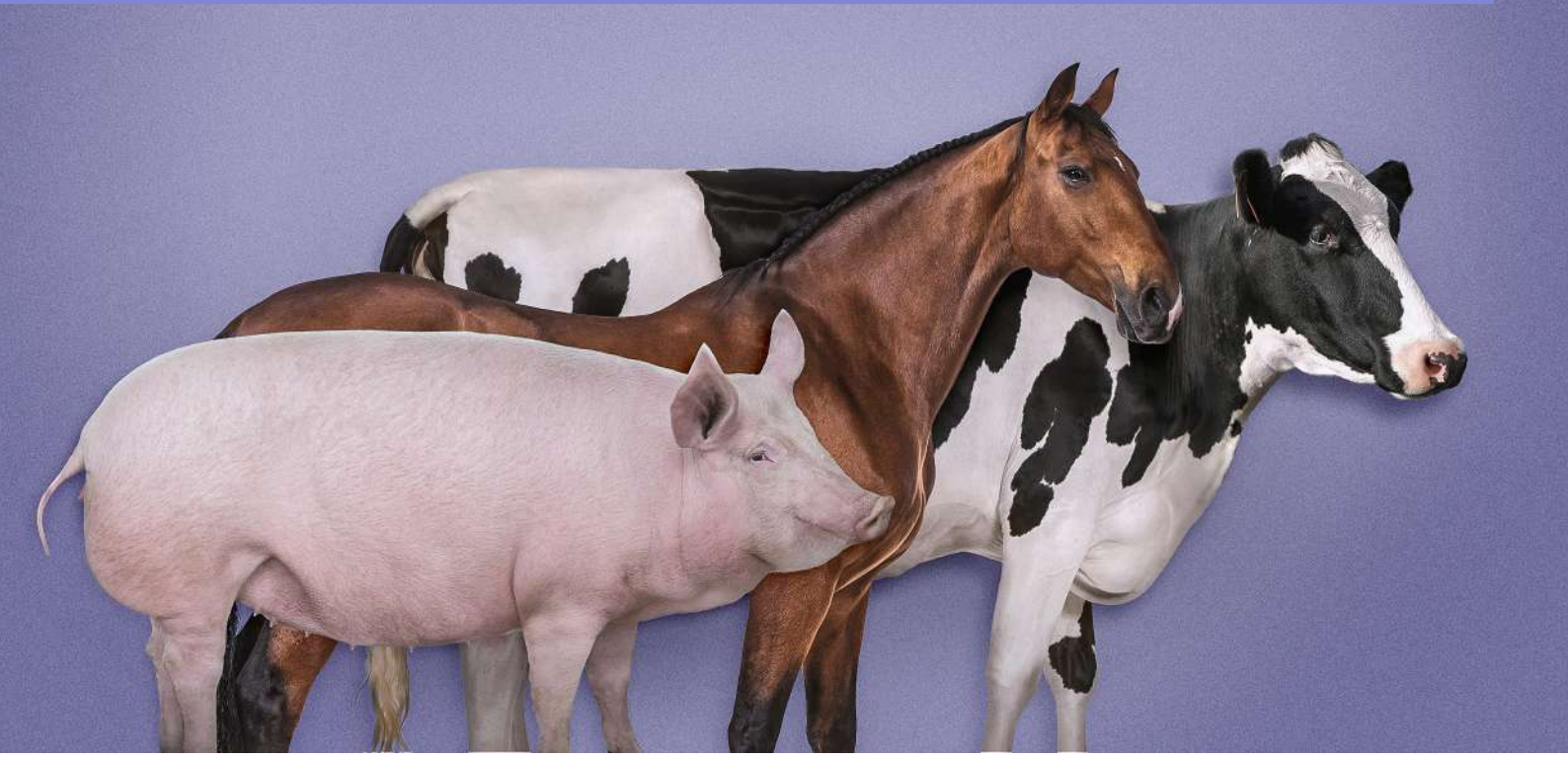
RECOCAM

20MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND HORSES

Meloxicam 20mg/ml

DATA SHEET



INDICATIONS

Cattle:

- For use in acute respiratory infections
- For use in diarrhoea in combination with oral re-hydration therapy in calves over one week of age
- For adjunctive therapy in the treatment of acute mastitis

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 toxaemia (mastitis-metritis-agalactia syndrome)

Horses:

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

BENEFITS

- **Multi-species**
- **Multi-indication**
- **IV or SC single injection course in cattle**

LIST No	UNIT PACKAGE	CASE SIZE
1REC016	100 ml	12

See reverse for Administration & Dosage

Recocam

20mg/ml Solution For Injection
For cattle, pigs and horses

PRESENTATION
A clear, yellow solution for injection containing 20 mg/ml meloxicam

TARGET SPECIES
Cattle, pigs and horses.

INDICATIONS FOR USE
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 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 toxaemia (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.

CONTRAINDICATIONS
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 cases 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.

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 PRODUCT
Accidental self-injection may give rise to pain.
People with known hypersensitivity to NSAIDs should avoid contact with the product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

ADVERSE REACTIONS
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 (less than 1 animal in 10,000 animals treated, including isolated reports) anaphylactoid reactions, which may be serious (including fatal), may occur and should be treated symptomatically.

USE DURING PREGNANCY AND LACTATION
Cattle and pigs: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.

INTERACTIONS
Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anti-coagulant agents.

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. 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 dose 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 dose 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, oral suspensions of meloxicam may be used for continuation of treatment 24 hours after administration of the injection.
Avoid introduction of contamination during use. Do not broach the stopper more than 50 times.

OVERDOSE
In the case of overdose, symptomatic treatment should be initiated.

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 for use in horses producing milk for human consumption.

PHARMACODYNAMIC PROPERTIES
Meloxicam belongs to the oxicam class of NSAIDs and 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.

PHARMACOKINETIC PARTICULARS
Absorption: After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/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 0.4 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 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. 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.

EXCIPIENTS
Ethanol 99.9%, Anhydrous citric acid, Poloxamer 188, Meglumine, Glycine, Macrogol 300, Sodium hydroxide (for pH adjustment), Hydrochloric acid (for pH adjustment), Water for injection .

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

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.

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

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

LEGAL CATEGORY
POM-V

MARKETING AUTHORISATION NUMBERS
EU/2/11/133/001-003

MARKETED IN THE UK BY
Bimeda UK
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Noah.co.uk/responsible

TAKE TIME  OBSERVE LABEL DIRECTIONS

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