Global Excellence in Animal Health

Bimeda®

Recocam 20 mg/ml

Meloxicam 20mg/ml

INDICATIONS

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.

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.

BENEFITS

- ✔ Proven Meloxicam formulation
- ✔ Long-lasting NSAID
- ✔ Convenient: one-injection-only course
- ✔ Cox 2-inhibitory activity mode of action
- ✔ Multi-species use
- ✔ Multi-indications use
- ✔ Licensed for calves with diarrhoea
- ✔ IV and SC route options in cattle

PACKAGING

List No	Unit Package
1REC001	100ml

See reverse for Administration & Dosage

www.bimeda.com

Recocam 20 mg/ml

Meloxicam 20mg/ml

Bimeda®

PRESENTATION
Clear yellow solution for injection containing:
Active substance per ml: Meloxicam 20 mg/ml

DOSAGE & 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, oral suspensions of meloxicam 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.
- **Do not** broach the stopper more than 50 times.

CONTRA-INDICATIONS & WARNINGS
Overdose (symptoms, emergency procedures, antidotes), if necessary
In the case of overdose, symptomatic treatment should be initiated

Special Precautions For Use In Animals

- **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.

- 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.

ADVERSE REACTIONS (FREQUENCY & 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.

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.
Do not use in horses producing milk for human consumption.

Interaction with other medicinal products and other forms of interaction
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

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.

PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids (oxicams)

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.

Pharmacokinetic particulars
Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, Cmax 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 Cmax 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.

LIST OF EXCIPIENTS
- Ethanol
- Anhydrous citric acid
- Poloxamer 188
- Meglumine
- Glycine
- Macrogol 300
- Sodium hydroxide (for pH adjustment)
- Hydrochloric acid (for pH adjustment)
- Water for injection

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

SHELF LIFE
After first opening the immediate packaging: 28 days

SPECIAL PRECUATIONS FOR STORAGE
This veterinary medicinal product does not require any special storage conditions

CLASSIFICATION:
UK POM-V

IRL POM

MARKETING AUTHORISATION HOLDER:
Cross Vetpharm Group Ltd

MARKETING AUTHORISATION NUMBER:
EU/2/11/133/001-003

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