Ceva Animal Health Ltd

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

Species: Cattle, Horses and other equidae, Pigs

Therapeutic indication:Pharmaceuticals: Anti-inflammatory preparations: Injections: NSAIDs

Active ingredient: Meloxicam

Product: Meloxidyl® 20 mg/ml solution for injection for cattle, pigs and horses

Product index: Meloxidyl injection for cattle, pigs and horses

Cattle - milk:120 hours

Cattle - meat:15 days

Pig - meat:5 days

Withdrawal notes: Horse meat and offal: 5 days

Incorporating:

Qualitative and quantitative composition

One ml of Meloxidyl 20 mg/ml solution for injection contains:

Active substance:
Meloxicam 20 mg

Excipient:
Ethanol anhydrous 150 mg

For the full list of excipients, see Pharmaceutical particulars.

Pharmaceutical form

Solution for injection. Clear, colourless to yellowish solution.

Clinical particulars

NOAH Compendium

Target species

Cattle, pigs and horses

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 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

See also section Use during pregnancy, lactation or lay.

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.

Special warnings for each target species

Treatment of calves with Meloxidyl 20 minutes before dehorning reduces post-operative pain.

Meloxidyl alone will not provide adequate pain relief during dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

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.

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 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.

See also Contraindications.

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.

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).

Avoid introduction of contamination during use.

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

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

Withdrawal period(s)

Cattle:

Meat and offal: 15 days

Milk: 5 days

Pigs:

Meat and offal: 5 days

Horses:

Meat and offal: 5 days.

Pharmacological particulars

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams)
ATCvet code: QM01AC06

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.

Pharmaceutical particulars

List of excipients

Ethanol, anhydrous, Poloxamer 188, Macrogol 300, Glycine, Sodium citrate, Sodium hydroxide (for pH adjustment), Hydrochloric acid (for pH adjustment), Meglumine, Water for injections.

Major incompatibilities

None known.

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

Shelf life after first opening the immediate packaging: 28 days.

Special precautions for storage

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

Nature and composition of immediate packaging

Cardboard box containing 1 colourless glass vial of 50 ml, 100 ml or 250 ml.

Each vial is closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

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.

Marketing Authorisation Holder (if different from distributor)

Marketing Authorisation Number

UK(GB): Vm 15052/5013

UK(NI): EU/2/06/070/005-007

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation: 15.01.2007

Date of last renewal: 19.12.2011

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/.

Any other information

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Legal category

Legal category:POM-V

GTIN

GTIN description: Meloxidyl 20 mg/ml 100 ml

GTIN:03411111946267

GTIN description: Meloxidyl 20 mg/ml 50 ml

NOAH Compendium

GTIN:03411111946199