emdocam® 20mg/ml

Emdocam 20mg/ml Solution for Injection for Cattle, Pigs and Horses

Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release:

Marketing authorisation holder:
Emdoka bvba., J. Lijsenstraat 16, B-2321 Hoogstraten, Belgium

Manufacturer for the batch release:
Produlab Pharma bv., NL-4941 SJ Raamsdonksveer, The Netherlands

Name of the veterinary medicinal product

Emdocam 20mg/ml Solution for Injection for Cattle, Pigs and Horses

Meloxicam

Statement of active substance(s) and other ingredients

One ml contains:
Meloxicam 20mg
Ethanol 150mg
Clear yellow solution for injection.

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.

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.

Contra-indications

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.

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.

Target species

Cattle, pigs and horses

Dosage for each species, routes and method of administration

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

Pigs: Single intramuscular injection at a dosage of 0.4mg meloxicam/kg body weight (*i.e.* 2.0ml/100kg 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 0.6mg meloxicam/kg body weight (*i.e.* 3.0ml/100kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo-skeletal disorders, a suitable oral therapy containing meloxicam, administered in accordance with label recommendations, may be used for continuation of treatment.

Advice on correct administration

Avoid introduction of contamination during use.
Do not broach the vial more than 50 times.

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.

Special storage precautions

Keep out of the reach and sight 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.

Special warnings

Treatment of calves with Emdocam 20 minutes before dehorning reduces post-operative pain. Emdocam 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: See section "Contraindications".

Interactions

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

Overdose

In case of overdose, symptomatic treatment should be initiated.

Specific precautions for the disposal of unused products or waste materials

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.

Date on which the package leaflet was last approved: August 2011

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

Other information

Cardboard box with 1 colourless Type I glass vial containing 50ml, 100ml or 250ml. Each vial is closed with a bromobutyl rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

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

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