SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 5 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam 5 mg

Excipients:
Ethanol 150 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (calves and young cattle) and pigs

4.2 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 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 the relief of post-operative pain associated with minor soft tissue surgery such as castration.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Cattle:

Do not use in cattle suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

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

Pigs:

Do not use in pigs suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in pigs less than 2 days old.

4.4 Special warnings for each target species

Cattle:

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 pain relief during surgery co-medication with an appropriate anaesthetic/sedative/analgesic is needed.

To obtain the best possible pain-relieving effect post-surgery Emdocam should be administered 30 minutes before surgical intervention.

Pigs:

Treatment of piglets with Emdocam before castration reduces post-operative pain.

To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative/analgesic is needed.

To obtain the best possible pain-relieving effect post-surgery Emdocam should be administered 30 minutes before surgical intervention.

4.5 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 severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydratation, as there may be a potential risk of renal toxicity.

During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Meloxicam may cause allergic reactions. People with known hypersensitivity to Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Accidental self-injection may give rise to pain. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

4.6 Adverse reactions (frequency and seriousness)

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. Anaphylactic reactions, which may be serious (including fatal), may occur in very rare cases and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Cattle: Can be used during pregnancy.

Pigs: Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.

Avoid introduction of contamination during use.

Cattle:
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e.10 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:
Locomotor disorders:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.
Reduction of post-operative pain:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

As the vial should not be broached more than 50 times the user should select the most appropriate vial size according to the target species to be treated.

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

In case of overdose symptomatic treatment should be initiated.

4.11 Withdrawal periods

Cattle (calves and young cattle)**:** Meat and offal: 15 days

Pigs: Meat and offal: 5 days

5. PHARMACOLOGICAL PROPERTIES

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

5.1 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. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cy clooxygenase-1 (COX-1). Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by *E. coli* endotoxin administration in calves and pigs.

5.2 Pharmacokinetic particulars

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 µg/ml were reached after 7.7 hours in young cattle.
Following single intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.1 to 1.5 µg/ml was reached within 1 hour in pigs.

Distribution
More than 98 % of meloxicam is bound to plasma proteins in cattle and pigs.
In cattle and pigs, 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 metabolized to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive. The main pathway of meloxicam biotransformation is oxidation.

Elimination
Meloxicam is eliminated with a half-life of 26 hours after subcutaneous injection in young cattle. In pigs, after intramuscular administration, 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Poloxamer 188
Sodium chloride
Glycine
Hydrochloric acid
Sodium hydroxide
Glycofurol
Meglumine
Water for injections

6.2 Major incompatibilities

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

6.3 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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Colourless type I glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Pack sizes:
Cardboard box containing 1 vial of 50 ml
Cardboard box containing 1 vial of 100 ml
Cardboard box containing 1 vial of 250 ml

Not all pack sizes may be marketed.

6.6 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.

7. MARKETING AUTHORISATION HOLDER

Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

8. MARKETING AUTHORISATION NUMBER

Vm 34534/5003

9. DATE OF FIRST AUTHORISATION

30 June 2021

10. DATE OF REVISION OF THE TEXT

June 2021

Approved 30 June 2021