

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:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Ethanol	150 mg
Poloxamer 188	
Sodium chloride	
Glycine	
Hydrochloric acid	
Sodium hydroxide	
Glycofurol	
Meglumine	
Water for injections	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves and young cattle) and pigs

3.2 Indications for use for each 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.

3.3 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.

3.4 Special warnings

Cattle:

Treatment of calves with the veterinary medicinal product minutes before dehorning reduces post-operative pain.

The veterinary medicinal product 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 the veterinary medicinal product should be administered 30 minutes before surgical intervention.

Pigs:

Treatment of piglets with the veterinary medicinal product 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 the veterinary medicinal product should be administered 30 minutes before surgical intervention.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 rehydration, 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves and young cattle):

Common (1 to 10 animals / 10,000 animals treated):	Injection site swelling ¹
Very rare (<1 animal / 10 000 animals treated, including isolated reports)	Anaphylactoid reaction ²

¹Following subcutaneous injection: slight and transient.

²May be serious (including fatal) and should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction ¹
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¹May be serious (including fatal) and should be treated symptomatically.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.

Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Cattle: Can be used during pregnancy.

Pigs: Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

For subcutaneous, intramuscular or intravenous use.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

Pigs: Meat and offal: 5 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AC06

4.2 Pharmacodynamics

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 cyclooxygenase-1 (COX-1). 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 and pigs.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka bvba

7. MARKETING AUTHORISATION NUMBER

Vm 34534/5003

8. DATE OF FIRST AUTHORISATION

30 June 2021

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 26 March 2026