

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Emdocam 5 mg/ml solution for injection for dogs and cats

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

**Active substance:**

Meloxicam 5 mg

**Excipients:**

<b>Qualitative composition of excipients and other constituents</b>	<b>Quantitative composition if that information is essential for proper administration of the veterinary medicinal product</b>
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**

Dogs, cats

#### **3.2 Indications for use for each target species**

**Dogs:**

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

**Cats:**

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

**3.3 Contraindications**

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

Do not use in dogs and cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

Do not use in dogs and cats less than 6 weeks of age nor in cats of less than 2 kg.

**3.4 Special warnings**

None.

**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.

Any oral follow-up therapy using meloxicam or other NSAIDs should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

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

#### Dogs, cats:

Rare (1 to 10 animals / 10,000 animals treated):	Appetite loss <sup>1</sup> , lethargy <sup>1</sup> Vomiting <sup>1</sup> , diarrhoea <sup>1</sup> , blood in faeces <sup>1,2</sup> Renal failure <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Haemorrhagic diarrhoea <sup>1</sup> , haematemesis <sup>1</sup> , gastric ulcer <sup>1</sup> , small intestine ulcer <sup>1</sup> Elevated liver enzymes <sup>1</sup> Anaphylactoid reaction <sup>3</sup>

<sup>1</sup>These adverse events occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

<sup>2</sup>Occult.

<sup>3</sup>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:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating animals.

### 3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

### 3.9 Administration routes and dosage

For subcutaneous 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.

**Dogs:**

Musculo-skeletal disorders:

Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).

Reduction of post-operative pain (over a period of 24 hours):

Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

**Cats:**

Reduction of post-operative pain:

Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.

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**

Not applicable

**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).

### **4.3 Pharmacokinetics**

#### Absorption

Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 µg/ml in dogs and 1.1 µg/ml in cats were reached approximately 2.5 hours and 1.5 hours post administration, respectively.

#### Distribution

There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs and cats. more than 97% of meloxicam is bound to plasma proteins in dogs and cats. 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. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

#### Metabolism

Meloxicam is predominantly found in plasma. It is also a major biliary excretion product in dogs and cats whereas urine contains only traces of the parent compound. In cats five major metabolites were detected all having been shown to be pharmacologically inactive. The main pathway of meloxicam biotransformation is oxidation.

#### Elimination

In dogs and cats, Meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine in dogs. In cats, the detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21 % of the recovered dose is eliminated in urine (2 % as unchanged meloxicam, 19 % as metabolites) and 79 % in the faeces (49 % as unchanged meloxicam, 30 % as metabolites).

## **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 20 ml

Cardboard box containing 1 vial of 50 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 34534/5004

**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](http://www.gov.uk).

*Gavin Hall*  
Approved: 26 March 2026