

## Material Safety Data Sheet

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

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

#### 1.1 Product identification

Product name(s):	Emdocam 20 mg/ml Solution for Injection for Cattle, Pigs and Horses
Product code(s):	XVD 220 (50 ml vial) XVD 222 (100 ml vial)

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:	Veterinary medicinal product
Uses advised against:	Not for human use. Refer to the product information leaflet
Reasons why uses advised against:	Refer to the product information leaflet

#### 1.3 Details of the supplier of the safety data sheet

Company name:	Animalcare Limited
Address:	10 Great Northway York Business Park Nether Poppleton York YO26 6RB United Kingdom

#### 1.4 Emergency telephone number

Daytime:	+44 (0) 1904 487687
----------	---------------------

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008	This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.
---	--

#### 2.2 Label elements

Labelling according to Regulation (EC) 1272/2008	This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.
Hazard pictograms:	Not applicable
Signal word:	Not applicable
Hazard statements:	Contact with skin may cause eye and skin irritation
Precautionary statements:	Wear protective gloves and eye/face protection. 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. Accidental human ingestion can cause serious reactions or anaphylactic reaction and systemic effects
Supplemental information:	Not applicable

#### 2.3 Other hazards

Hazard(s) not otherwise classified (HNOC)	None known
---	------------

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Meloxicam	[71125-38-72]	2%
Ethanol	[64-17-5]	Proprietary
Meglumine	[6284-40-8]	Proprietary
Polyethylene glycol 300	[25322-68-3]	Proprietary
Poloxamer 188	[9003-11-6]	Proprietary
Glycine	[56-40-6]	Proprietary
Sodium hydroxide	[1310-73-2]	Proprietary
Hydrochloric acid	[7647-01-0]	Proprietary
Water	[7732-18-5]	Proprietary

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Eyes:</b>	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention
<b>Skin:</b>	In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if symptoms occur
<b>Ingestion:</b>	Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person
<b>Inhalation:</b>	Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist
<b>Injection:</b>	In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician

### 4.2 Most important symptoms and effects, both acute and delayed

The most common reactions are anorexia, nausea and diarrhea.

### 4.3 Indication of any immediate medical attention and special treatment needed

When administering any NSAID, appropriate lab testing to establish hematological and serum biochemical baseline data is recommended prior to use

## SECTION 5: FIRE- FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media:</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use carbon dioxide, dry chemicals, water spray or foam
<b>Unsuitable extinguishing media:</b>	Water Jet. USE WATER WITH CAUTION. Material will float and may ignite on the surface of the water. Use water spray to keep fire-exposed containers cool. Water may be ineffective in fighting the fire

### 5.2 Special hazards arising from the substance or mixture

<b>Specific hazards during firefighting:</b>	Flammability class IC
<b>Hazardous combustion products:</b>	Decomposition products may include the following materials: Carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ). Vapors may cause a flash fire or ignite explosively. Vapors may travel considerable distance to a source of ignition and flash back. Prevent build-up of vapors to explosive concentrations

### 5.3 Advice for fire-fighters

**Special protective equipment for firefighters:** Wear self-contained breathing apparatus and protective clothing

**Further information:** Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

**Advice for non-emergency personnel:** Refer to protective measures listed in sections 7 and 8

**Advice for emergency responders:** If specialised clothing is required to deal with the spillage, take note of any information in section 8 on suitable and unsuitable materials

### 6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

### 6.3 Methods and material for containment and cleaning up

**Large spills:** Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers

**Small spills:** Eliminate all ignition sources. Use water to disperse vapors and dilute spill to a nonflammable mixture. Use a non-combustible material like vermiculite, earth or sand to soak up the product and place into container for later disposal

### 6.4 Reference to other sections

See Section 1 for emergency contact information

See section 8 for personal protection

See Section 13 for additional waste treatment information

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

**Advice on safe handling:** Avoid contact with eyes, skin and clothing. Do not taste or swallow. Use only with adequate ventilation

**Hygiene measures:** Wash thoroughly with soap and water after handling

### 7.2 Conditions for safe storage, including any incompatibilities

**Requirements for storage areas and containers:** Keep out of reach of children. Keep in the original packaging

**Storage temperature:** Store at ambient temperature

**Further information on storage conditions:** Protect from direct incidence of light

### 7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

## SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. None established.

## 8.2 Exposure controls

<b>Engineering measures:</b>	Not generally required when handling vials or containers. Good ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level
<b>Individual protection measures:</b>	
<b>Hygiene measures:</b>	Eye bath, washing facilities, shower
<b>Eye/face protection:</b>	Wear safety glasses with side shields (or goggles)
<b>Skin/body protection:</b>	Wear protective clothing appropriate for the risk of exposure
<b>Hand protection:</b>	Wear suitable gloves
<b>Respiratory protection:</b>	Not generally required when handling vials or containers. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA standard 63 FR 1152, January 8, 1998. Respirator type: NIOSH approved organic vapor respirator.
<b>Environmental exposure controls:</b>	Consider the provision of containment around storage vessels

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Liquid
<b>Colour:</b>	Yellow
<b>Odour:</b>	Alcoholic odour
<b>Odour threshold:</b>	No data available
<b>pH:</b>	Approx. 8.8
<b>Density:</b>	No data available
<b>Melting point:</b>	No data available
<b>Boiling point:</b>	No data available
<b>Flash point:</b>	36.6 °C
<b>Evaporation rate:</b>	No data available
<b>Flammability:</b>	No data available
<b>Water solubility:</b>	No data available
<b>Partition coefficient:</b>	No data available
<b>Auto-ignition temperature:</b>	No data available
<b>Thermal decomposition:</b>	No data available
<b>Viscosity:</b>	No data available
<b>Vapour pressure:</b>	No data available
<b>Vapour density:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	The substance or mixture is not classified as oxidizing

### 9.2 Other information

No data available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

### 10.2 Chemical stability

Stable under normal conditions

### 10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

### 10.4 Conditions to avoid

Avoid contact with incompatible materials

### 10.5 Incompatible materials

Strong oxidizing agents

### 10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity:

Meloxicam LD<sub>50</sub> 84 mg/kg (Rat, oral)  
Meloxicam LD<sub>50</sub> 470 mg/kg (Mouse, oral)  
Meloxicam LD<sub>50</sub> 320 mg/kg (Rabbit, oral)

#### Chronic toxicity:

Repeated-dose toxicity was evaluated in three strains of rats (Chbb:THOM, Sprague Dawley and Wistar (intravenously: 4 weeks, orally: 4, 13,26, 52, 78 weeks)), mice (orally: 13 weeks), micro- and mini-pigs (intravenously: 4 and 5 weeks and orally: 13 and 52 weeks). Shorter term tolerance studies were also performed in dogs (orally: 3 and 4 weeks). Doses in rats, mice, pigs and dogs were in the dose range of 0.2-10 mg/kg bw, 8-35 mg/kg bw, 1-10 mg/kg bw and 0.1-1.2 mg/kg bw, respectively. The primary target organs for toxicity were the gastrointestinal tract and kidneys. Deaths during treatment with meloxicam were associated with gastric and renal toxicity. Gastrointestinal lesions consisted of ulcers, particularly in the pyloric region of the stomach, but also in the duodenum and in some animals further along the small intestine, coagulated blood in gastrointestinal tract, peritonitis, gastric erosion, gastric dilation and/or callous thickening. Renal changes consisted of scarring, granular surface, presence of gritty concretions, necrosis and pyelonephritis. Organ weight analysis revealed weight increases of the spleen and kidneys. Once the treatment ceased the severity of toxicity and extent of reversibility were dependent on dose and duration of treatment. Female rats were more severely affected than male rats, consistent with higher blood levels of meloxicam in females compared to males. The sex difference in sensitivity was not observed in mini-pigs and mice. In rats the oral NOEL could be established to 0.2 mg/kg bw, in the 52-week feeding study in Wistar rats as well as after intravenous treatment for 4 weeks in Chbb:THOM rats. Minipigs were relatively insensitive to meloxicam with a NOEL of 1 mg/kg bw derived from a 13 weeks and a 52 weeks study following oral administration. In dogs a NOEL of 0.4 mg/kg bw was determined in the 4-week study. However, in the 3-week study occult blood was observed even in the lowest dose (0.4 mg/kg bw) and a NOEL could not be determined.

#### Skin irritation/sensitization:

No data available

#### Reproductive toxicity:

No data available

#### Carcinogenicity:

No data available

#### Mutagenicity:

Teratogenicity studies have been performed in rats (strains: Sprague Dawley and Chbb:THOM) and rabbits (Chbb:HM) at doses of 1-4 mg/kg bw in rats and 1-80

mg/kg in rabbits. There was no evidence for teratogenic activity in these studies. However, meloxicam showed embryotoxic effects at the lowest doses tested (1 mg/kg) in Chbb:THOM rats and in rabbits. For maternotoxicity, NOELs of 1 and 20 mg/kg bw were identified in Chbb:THOM rats and rabbits, respectively.

## **SECTION 12: ECOLOGICAL INFORMATION**

### **12.1 Toxicity**

No data available

### **12.2 Persistence and degradability**

No data available

### **12.3 Bioaccumulative potential**

No data available

### **12.4 Mobility in soil**

No data available

### **12.5 Results of PBT and vPvB assessment**

No data available

### **12.6 Other adverse effects**

No data available

## **SECTION 13: DISPOSAL CONSIDERATIONS**

### **13.1 Waste treatment methods**

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

## **SECTION 14: TRANSPORT INFORMATION**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

## **SECTION 15: REGULATORY INFORMATION**

### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

This product has been authorised under the provisions of Directive 2001/82/EC

### **15.2 Chemical safety assessment**

For this product, a chemical safety assessment was not carried out

## **SECTION 16: OTHER INFORMATION**

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

---

End of document