



Complying to 91/155/EC, 93/112/EC

Product Safety Data Sheet

Emdocam 20 mg/ml

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	EMDOCAM 20 mg/ml Solution for Injection for Cattle, Pigs and Horses
Product Code	XVD 220: 50ml bottle XVD 222: 100ml bottle
Supplier	Animalcare Ltd, Common Road, Dunnington, York, YO19 5RU. Telephone No. +44 (0) 1904 487687 Fax No. +44 (0) 1904 487611 E-Mail: animalcare@animalcare.co.uk. Emergency Telephone +44 (0) 1904 487687 (daytime)

2. HAZARDS IDENTIFICATION

WARNING!

Not for human use.

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.



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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.

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

Fire-fighting: Use carbon dioxide, dry chemicals, water spray, foam or material appropriate for the surrounding fire.

Avoid contact with eyes, skin and clothing.

Wash thoroughly with soap and water after handling.

Spills: Cover with absorbent or contain. Collect and dispose.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If swallowed, seek medical advice immediately and show this container or label.

This material and its container must be disposed of in a safe way.

Keep out of reach of children.

Potential Health Effects

Inhalation:	Not expected to be an inhalation hazard.
Eye Contact:	Not expected to be a hazard to the eye with prescribed use. Causes eye irritation. Exposure may cause eye tearing, redness, and discomfort.
Skin Contact:	Not expected to be a hazard to the skin with prescribed use. Causes skin irritation. Exposure may cause redness, itching and inflammation.
Ingestion:	Not expected to be an ingestion hazard with prescribed use. Ingestion may cause vomiting, nausea or other systemic effects.
Injection:	Not applicable
Chronic Health Effects:	Possible hypersensitization (development of abnormal sensitivity).



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Target Organ(s): Gastrointestinal tract, kidneys, liver.
OSHA Regulatory Status: Nonhazardous, exempt.
Environment: No data available.

3. COMPOSITION / INFORMATION ON COMPONENTS

Ingredient	CAS	Concentration %
Meloxicam	71125-38-72	2
Ethanol	64-17-5	15
Meglumine	6284-40-8	
Polyethylene glycol 300	25322-68-3	
Poloxamer 188	9003-11-6	
Glycine	56-40-6	
Sodium hydroxide	1310-73-2	pH = appr. 8.8
Hydrochloric acid	7647-01-0	
Water for Injections	7732-18-5	

4. FIRST AID MEASURES

General: Animals or persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

Inhalation: Move to fresh air. Treat symptomatically. Get medical attention if symptoms persist.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.



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Skin Contact:	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.
Ingestion:	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.
Injection:	In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Note to Physician:	For injection in cattle, pigs and horses only. Not for human use.
Antidote:	Epinephrine is indicated for anaphylactoid reactions.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemicals, water spray or foam.

Unsuitable Extinguishing

Media: 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.

Special Fire Fighting

Procedures: Wear self-contained breathing apparatus and protective clothing.

Unusual Fire &

Explosion Hazards: 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.

Hazardous Combustion

Products: Carbon monoxide, carbon dioxide

Flammability Class: IC



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6. ACCIDENTAL RELEASE MEASURES

Personal

Precautions: Wear appropriate personal protective equipment. See section 8.

Spill Cleanup

Methods: Small liquid spill: 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.

For large liquid spill: Absorb or cover with dry earth, sand or other non-combustible material and transfer to containers..

Environmental

Precautions: Flush spill area with water spray. Prevent runoff from entering drains, sewers or streams. Dike for later disposal.

7. HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly with soap and water after handling. Use only with adequate ventilation.

Fire and Explosion

Protection: Keep away from heat, sparks and flame. Keep from contact with oxidizing materials. Comply with all national, state and local codes pertaining to the storage, handling, dispensing and disposal of flammable liquids.

Storage: This veterinary medicinal product does not require any special storage conditions. Keep out of reach of children. Keep away from food, drink and animal feedstuffs.



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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

For Exposures:

Exposure Limits: Check local exposure limits. Wear protective clothes.

Engineering

Controls: 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.

Respiratory

Protection: 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.

Respirator type: NIOSH approved organic vapor respirator.

PERSONAL PROTECTIVE EQUIPMENT:

Not generally required when handling containers. If containers are compromised or exposure to the active ingredient or mixture is likely wear:

Eye Protection: Wear safety glasses with side shields (or goggles).

Hand Protection: Wear suitable gloves.

Skin Protection: Wear protective clothing appropriate for the risk of exposure.

Hygiene Measures: Eye bath, washing facilities, shower.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	Yellow.
Odor:	Alcoholic odour.
Odor Threshold:	No data available.
Physical State:	Liquid 20 mg/mL.
pH:	appr 8.8.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	36.6 °C.
Flammability Limit – Upper (%):	Not applicable.
Flammability Limit – Lower (%):	Not applicable.
Evaporation rate:	No data available.
Vapor Pressure:	No data available.
Vapor Density (Air=1):	No data available.
Solubility:	Insoluble.
Partition Coefficient	
(n-Octanol/water):	No data available.
Autoignition Temperature:	No data available.
Decomposition Temperature:	No data available.

10. STABILITY AND REACTIVITY

Stability:	Stable.
Conditions to Avoid:	None known.



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Incompatible Materials: Strong oxidizing agents.

Hazardous Decomposition

Products: None known.

Possibility of Hazardous

Reactions: Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION¹

Acute Toxicity

Chemical Name	Test Results
2H-1,2-Benzothiazine-3-carboxamide,	Oral LD ₅₀ (rat): 84 mg/kg
4-hydroxy-2-methyl-N-	Oral LD ₅₀ (mouse): 470 mg/kg
(5-methyl-2-thiazolyl)-1, 1-dioxide	Oral LD ₅₀ (rabbit): 320 mg/kg

¹ EMEA MRL Summary reports - EMEA/MRL/236/97-FINAL – Anonymous – June 1997

Sub-acute/Long term 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.



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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.

Teratogenicity

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 bw 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 bw) 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.

12. ECOLOGICAL INFORMATION

Ecotoxicity:	No data available.
Persistence and degradability:	No data available.
Mobility in soil:	No data available.



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Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

General Information: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Disposal Methods: No specific disposal method required. Do not empty into drains; dispose of this material and its container in a safe way. Do not contaminate water, food, or feed by storage disposal.

RCRA Information: Not applicable.

Container: Since emptied containers retain product residue, follow label warnings even after container is emptied.

14. TRANSPORT INFORMATION

DOT: Not regulated.

TDG: Not regulated.

ADR: Not regulated.

RID: Not regulated.

IATA: Not regulated.

IMDG: Not regulated.

15. REGULATORY INFORMATION

Austria MAK List (Annex I): None

Denmark (Annex 3.6, April 2005): None



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Germany (Dangerous Substances

Ordinance 2004, Annex III): None

Norway (List of Dangerous

Substance): None

Sweden (Sensitizers- Annex 3): None

Switzerland (Toxins List 1): None

16. OTHER INFORMATION

Hazard Ratings

	Health Hazard	Fire Hazard	Reactivity Hazard	
HMIS	2	0	0	
	Health Hazard	Fire Hazard	Reactivity Hazard	Special Hazard
NFPA	2	0	0	N/A

*- Chronic health effect; 0 – Minimal; 1 – Slight; 2 – Moderate; 3 – Serious; 4 – Severe

Xi- Irritation

R36- Irritating to eyes.

R38-Irritating to skin.

S25- Avoid contact with eyes.

S26-In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S7- Keep container closed.

S24 - Avoid contact with skin.

S37 – Wear suitable gloves.



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