

NADA 141-213, Approved by FDA

Metacam®

(meloxicam)

1.5 mg/mL Oral Suspension (equivalent to 0.05 mg per drop)

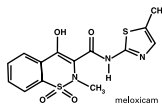
0.5 mg/mL Oral Suspension (equivalent to 0.02 mg per drop)

Non-steroidal anti-inflammatory drug for oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Warning: Repeated use of meloxicam in cats has been associated with acute renal failure and death. Do not administer additional injectable or oral meloxicam to cats. See Contraindications, Warnings, and Precautions for detailed information.

Description: Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class. Each milliliter of Metacam Oral Suspension contains meloxicam equivalent to 0.5 or 1.5 milligrams and sodium benzoate (1.5 milligrams) as a preservative. The chemical name for Meloxicam is 4-Hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide. The formulation is a yellowish viscous suspension with the odor of honey.



Indications: Metacam Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Always provide client information sheet with prescription. Carefully consider the potential benefits and risk of Metacam and other treatment options before deciding to use Metacam. Use the lowest effective dose for the shortest duration consistent with individual response. Metacam Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, Metacam Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The syringe is calibrated to deliver the daily maintenance dose in pounds.

Directions for Administration (1.5 mg/mL strength):

Dogs under 10 pounds (4.5 kg)

Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth. Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog. The syringe provided with the meloxicam concentration of 1.5 mg/mL cannot be used to measure doses for dogs weighing less than 5 lbs (2.3 kg).

For dogs less than 5 lbs (2.3 kg), Metacam Oral Suspension can be given using the dropper bottle: one drop for each pound of body weight for the 1.5 mg/mL concentration (two drops for each kilogram of body weight), dropped directly onto the food.

For dogs between 5-10 pounds, Metacam Oral Suspension can be given by drops or by using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale beginning at 5 lbs, designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 5 pound increment. Replace and tighten cap after use.

Dogs over 10 pounds (4.5 kg)

Shake well before use then remove cap. Metacam Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given with regard to the accuracy of dosing. Metacam Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale in pounds designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 5 pound increment. Alternatively, Metacam Oral Suspension can be given using the dropper bottle: one drop for each pound of body weight for the 1.5 mg/mL concentration (two drops for each kilogram of body weight). Replace and tighten cap after use.

Directions for Administration (0.5 mg/mL strength):

Dogs under 10 pounds (4.5 kg)

Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth. Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog. The syringe provided with the meloxicam concentration of 0.5 mg/mL cannot be used to measure doses for dogs weighing less than 1 lb (0.45 kg).

For dogs less than 1 lb (0.45 kg), Metacam Oral Suspension can be given using the dropper bottle: two drops for each pound of body weight for the 0.5 mg/mL concentration (five drops for each kilogram of body weight), dropped directly onto the food.

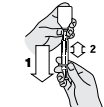
For dogs between 1-10 pounds, Metacam Oral Suspension can be given by drops or by using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale beginning at 1 lb, designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 1 pound increment. Replace and tighten cap after use.

Dogs over 10 pounds (4.5 kg)

Shake well before use then remove cap. Metacam Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given with regard to the accuracy of dosing. Metacam Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale in pounds designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 1 pound increment. Alternatively, Metacam Oral Suspension can be given using the dropper bottle: two drops for each pound of body weight for the 0.5 mg/mL concentration (five drops for each kilogram of body weight). Replace and tighten cap after use.



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end on to the top of the bottle.



Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to the dog's body weight in pounds.



Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.



Push the plunger to empty the contents of the syringe.

Contraindications: Dogs with known hypersensitivity to meloxicam should not receive Metacam Oral Suspension. Do not use Metacam Oral Suspension in cats. Acute renal failure and death have been associated with the use of meloxicam in cats.

Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. For oral use in dogs only.

As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. Owner should be advised to observe their dog for signs of potential drug toxicity and be given a client information sheet about Metacam.

Precautions: The safe use of Metacam Oral Suspension in dogs younger than 6 months of age, dogs used for breeding, or in pregnant or lactating dogs has not been evaluated. Meloxicam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders. As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Dogs that have experienced adverse reactions from one NSAID may experience adverse reactions from another NSAID. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects may result in clinically significant disease in patients with underlying or pre-existing disease that has not been previously diagnosed. Since NSAIDs possess the potential to induce gastrointestinal ulcerations and/or perforations, concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided. If additional pain medication is needed after administration of the total daily dose of Metacam Oral Suspension, a non-NSAID or non-corticosteroid class of analgesia should be considered. The use of another NSAID is not recommended. Consider appropriate washout times when switching from corticosteroid use or from one NSAID to another in dogs. The use of concomitantly protein-bound drugs with Metacam Oral Suspension has not been studied in dogs. Commonly used protein-bound drugs include cardiac, anticonvulsant and behavioral medications. The influence of concomitant drugs that may inhibit metabolism of Metacam Oral Suspension has not been evaluated. Drug compatibility should be monitored in patients requiring adjunctive therapy.

Adverse Reactions: Field safety was evaluated in 306 dogs. Based on the results of two studies, GI abnormalities (vomiting, soft stools, diarrhea, and inappetence) were the most common adverse reactions associated with the administration of meloxicam. The following table lists adverse reactions and the numbers of dogs that experienced them during the studies. Dogs may have experienced more than one episode of the adverse reaction during the study.

| Adverse Reactions Observed During Two Field Studies | | |
|---|-------------------|-----------------|
| Clinical Observation | Meloxicam (n=157) | Placebo (n=149) |
| Vomiting | 40 | 23 |
| Diarrhea/Soft Stool | 19 | 11 |
| Bloody Stool | 1 | 0 |
| Inappetence | 5 | 1 |
| Bleeding gums after dental procedure | 1 | 0 |
| Lethargy/Swollen Carpus | 1 | 0 |
| Epiphora | 1 | 0 |

In foreign suspected adverse drug reaction (SADR) reporting over a 9 year period, incidences of adverse reactions related to meloxicam administration included: auto-immune hemolytic anemia (1 dog), thrombocytopenia (1 dog), polyarthritis (1 dog), nursing puppy lethargy (1 dog), and pyoderma (1 dog).

Post-Approval Experience (Rev. 2010): The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA/CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data. The following adverse events are listed in decreasing order of frequency by body system.

Gastrointestinal: vomiting, anorexia, diarrhea, melena, gastrointestinal ulceration

Urinary: azotemia, elevated creatinine, renal failure

Neurological/Behavioral: lethargy, depression

Hepatic: elevated liver enzymes

Dermatologic: pruritus

Death has been reported as an outcome of the adverse events listed above. **Acute renal failure and death have been associated with use of meloxicam in cats.**

To report suspected adverse drug events, for technical assistance, or to obtain a copy of the MSDS, contact Boehringer Ingelheim Vetmedica, Inc. at 1-866-METACAM (1-866-638-2226). For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

Information for Dog Owners: Metacam, like other drugs of its class, is not free from adverse reactions. Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with drug intolerance. Adverse reactions may include vomiting, diarrhea, decreased appetite, dark or tarry stools, increased water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, incoordination, seizure, or behavioral changes. **Serious adverse reactions associated with this drug class can occur without warning and in rare situations result in death (see Adverse Reactions).** Owners should be advised to discontinue Metacam and contact their veterinarian immediately if signs of intolerance are observed. The vast majority of patients with drug related adverse reactions have recovered when the signs are recognized, the drug is withdrawn, and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow up for all dogs during administration of any NSAID.

Clinical Pharmacology: Meloxicam has nearly 100% bioavailability when administered orally with food. The terminal elimination half life after a single dose is estimated to be approximately 24 hrs (+/-30%) regardless of route of administration. There is no evidence of statistically significant gender differences in drug pharmacokinetics. Drug bioavailability, volume of distribution, and total systemic clearance remain constant up to 5 times the recommended dose for use in dogs. However, there is some evidence of enhanced drug accumulation and terminal elimination half-life prolongation when dogs are dosed for 45 days or longer.

Peak drug concentrations can be expected to occur within about 7.5 hrs after oral administration. Corresponding peak concentration is approximately 0.464 mcg/mL following a 0.2 mg/kg oral dose. The drug is 97% bound to canine plasma proteins.

Effectiveness: The effectiveness of meloxicam was demonstrated in two field studies involving a total of 277 dogs representing various breeds, between six months and sixteen years of age, all diagnosed with osteoarthritis. Both of the placebo-controlled, masked studies were conducted for 14 days. All dogs received 0.2 mg/kg meloxicam on day 1. All dogs were maintained on 0.1 mg/kg oral meloxicam from days 2 through 14 of both studies. Parameters evaluated by veterinarians included lameness, weight-bearing, pain on palpation, and overall improvement. Parameters assessed by owners included mobility, ability to rise, limping, and overall improvement. In the first field study (n=109), dogs showed clinical improvement with statistical significance after 14 days of meloxicam treatment for all parameters. In the second field study (n=48), dogs receiving meloxicam showed a clinical improvement after 14 days of therapy for all parameters; however, statistical significance was demonstrated only for the overall investigator evaluation on day 7, and for the owner evaluation on day 14.

Palatability: Metacam Oral Suspension was accepted by 100% of the dogs when veterinarians administered the initial dose into the mouth. Metacam Oral Suspension was accepted by 90% of the dogs (123/136) when administered by owners. Problems associated with administration included refusal of food, resistance to swallowing and salivation.

Safety:

Six Week Study

In a six week target animal safety study, meloxicam was administered orally at 1, 3, and 5X the recommended dose with no significant clinical adverse reactions. Animals in all dose groups (control, 1, 3, and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). No treatment-related changes were observed in hematological, blood chemistry, urinalysis, clotting time, or buccal mucosal bleeding times. Necropsy results included stomach mucosal petechiae in one control dog, two dogs at the 3X and one dog at the 5X dose. Other macroscopic changes included areas of congestion or depression of the mucosa of the jejunum or ileum in three dogs at the 1X dose and in two dogs at the 5X dose. Similar changes were also seen in two dogs in the control group. There were no macroscopic small intestinal lesions observed in dogs receiving the 3X dose. Renal enlargement was reported during the necropsy of two dogs receiving the 3X dose and two receiving the 5X dose. Microscopic examination of the kidneys revealed minimal degeneration or slight necrosis at the tip of the papilla in three dogs at the 5X dose. Microscopic examination of the stomach showed inflammatory mucosal lesions, epithelial regenerative hyperplasia or atrophy, and submucosal gland inflammation in two dogs at the recommended dose, three dogs at the 3X and four dogs at the 5X dose. Small intestinal microscopic changes included minimal focal mucosal erosion affecting the villi, and were sometimes associated with mucosal congestion. These lesions were observed in the ileum of one control dog and in the jejunum of one dog at the recommended dose and two dogs at the 5X dose.

Six Month Study

In a six month target animal safety study, meloxicam was administered orally at 1, 3, and 5X the recommended dose with no significant clinical adverse reactions. All animals in all dose groups (controls, 1, 3, and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). Treatment related changes seen in hematology and chemistry included decreased red blood cell counts in seven of 24 dogs (four 3X and three 5X dogs), decreased hematocrit in 18 of 24 dogs (including three control dogs), dose-related neutrophilia in one 1X, two 3X and three 5X dogs, evidence of regenerative anemia in two 3X and one 5X dog. Also noted were increased BUN in two 5X dogs and decreased albumin in one 5X dog.

Endoscopic changes consisted of reddening of the gastric mucosal surface covering less than 25% of the surface area. This was seen in three dogs at the recommended dose, three dogs at the 3X dose and two dogs at the 5X dose. Two control dogs exhibited reddening in conjunction with ulceration of the mucosa covering less than 25% of the surface area. Gross gastrointestinal necropsy results observed included mild discoloration of the stomach or duodenum in one dog at the 3X and in one dog at the 5X dose. Multifocal pinpoint red foci were observed in the gastric fundic mucosa in one dog at the recommended dose, and in one dog at the 5X dose.

No macroscopic or microscopic renal changes were observed in any dogs receiving meloxicam in this six month study. Microscopic gastrointestinal findings were limited to one dog at the recommended dose, and two dogs at the 3X dose. Mild inflammatory mucosal infiltrate was observed in the duodenum of one dog at the recommended dose. Mild congestion of the fundic mucosa and mild myositis of the outer mural musculature of the stomach were observed in two dogs receiving the 3X dose.

How Supplied:

Metacam Oral Suspension 1.5 mg/mL: 10, 32, 100 and 180 mL dropper bottles with measuring syringe.

Metacam Oral Suspension 0.5 mg/mL: 15 mL and 30 mL dropper bottles with measuring syringe.

Storage: Store at controlled room temperature, 68-77°F (20-25°C). Excursions permitted between 59° and 86°F (15° and 30°C). Brief exposure to temperatures up to 104°F (40°C) may be tolerated provided the mean kinetic temperature does not exceed 77°F (25°C); however, such exposure should be minimized.

Manufactured for:

Boehringer Ingelheim Vetmedica, Inc.

St. Joseph, MO 64506 U.S.A.

US Patent 6,184,220

Metacam is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, licensed to Boehringer Ingelheim Vetmedica, Inc.

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Revised 08/2014

601501-03

08/2014

SAFETY DATA SHEET

1. Identification

| | |
|---|---|
| Product identifier | Metacam® (meloxicam) 0.5 mg/mL Oral Suspension for Dogs |
| Other means of identification | None. |
| Recommended use | For the control of pain and inflammation associated with osteoarthritis in dogs. |
| Recommended restrictions | None known. |
| Manufacturer/Importer/Supplier/Distributor information | |
| Manufacturer | Boehringer Ingelheim Vetmedica, Inc. |
| Address | 2621 North Belt Hwy St. Joseph, MO 64506-2002 |
| Transportation emergency | For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 Outside USA and Canada: +1 703-527-3887 (collect calls accepted) |
| Medical Emergency (24HR): | (866)638-2226 |
| Non-Emergency calls: | (800) 821-7467 |

2. Hazard(s) identification

| | |
|--|--|
| Physical hazards | Not classified. |
| Health hazards | Not classified. |
| OSHA defined hazards | Not classified. |
| Label elements | |
| Hazard symbol | None. |
| Signal word | None. |
| Hazard statement | The mixture does not meet the criteria for classification. |
| Precautionary statement | |
| Prevention | Observe good industrial hygiene practices. |
| Response | Wash hands after handling. |
| Storage | Store away from incompatible materials. |
| Disposal | Dispose of waste and residues in accordance with local authority requirements. |
| Hazard(s) not otherwise classified (HNOC) | None known. |
| Supplemental information | None. |

3. Composition/information on ingredients

Mixtures

| Chemical name | CAS number | % |
|---------------|------------|------|
| Meloxicam | 71125-38-7 | <0.1 |

4. First-aid measures

| | |
|---|---|
| Inhalation | If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist. |
| Skin contact | Rinse skin with water/shower. Get medical attention if irritation develops and persists. |
| Eye contact | Rinse with water. Get medical attention if irritation develops and persists. |
| Ingestion | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. |
| Most important symptoms/effects, acute and delayed | Direct contact with eyes may cause temporary irritation. Ingestion of a large quantity may cause nausea and systemic effects. |

| | |
|---|--|
| Indication of immediate medical attention and special treatment needed | Not for human use. For use in animals only. Treat symptomatically. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. |
| General information | Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. |
| 5. Fire-fighting measures | |
| Suitable extinguishing media | Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). |
| Unsuitable extinguishing media | None known. |
| Specific hazards arising from the chemical | During fire, gases hazardous to health may be formed. Combustion products may include: carbon oxides, nitrogen oxides. |
| Special protective equipment and precautions for firefighters | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| Fire fighting equipment/instructions | Move containers from fire area if you can do so without risk. |
| Specific methods | Use standard firefighting procedures and consider the hazards of other involved materials. |
| General fire hazards | No unusual fire or explosion hazards noted. |
| 6. Accidental release measures | |
| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up | Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. |
| | Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. |
| | Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |
| 7. Handling and storage | |
| Precautions for safe handling | Avoid prolonged exposure. Use care in handling/storage. |
| Conditions for safe storage, including any incompatibilities | Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Store away from foodstuffs. Store material between 15°C (59°F) and 30°C (86°F). |
| 8. Exposure controls/personal protection | |
| Occupational exposure limits | No exposure limits noted for ingredient(s). |
| Biological limit values | No biological exposure limits noted for the ingredient(s). |
| Appropriate engineering controls | Good general ventilation 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. |
| Individual protection measures, such as personal protective equipment | |
| Eye/face protection | Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear safety glasses with side shields (or goggles). |
| Skin protection | |
| Hand protection | Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear suitable gloves. |
| Other | Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear lab coat, apron or appropriate clothing to prevent skin contact. |
| 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. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Respirator type: NIOSH approved organic vapor respirator. |
| Thermal hazards | Wear appropriate thermal protective clothing, when necessary. |

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties**Appearance**

| | |
|---|------------------------|
| Physical state | Liquid. |
| Form | Liquid suspension |
| Color | Yellowish. |
| Odor | Honey |
| Odor threshold | Not available. |
| pH | 3.5 - 4.5 |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not available. |
| Flash point | > 199.9 °F (> 93.3 °C) |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not applicable. |

Upper/lower flammability or explosive limits

| | |
|--------------------------------|----------------|
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |

| | |
|------------------|------------------|
| Vapor pressure | Not available. |
| Vapor density | Not available. |
| Relative density | 1.56 (water = 1) |

Solubility(ies)

| | |
|---|----------------|
| Solubility (water) | Insoluble |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |

Other information

| | |
|----------------------|----------------|
| Explosive properties | Not explosive. |
| Oxidizing properties | Not oxidizing. |

10. Stability and reactivity

| | |
|------------------------------------|---|
| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. |
| Hazardous decomposition products | No hazardous decomposition products are known. |

11. Toxicological information**Information on likely routes of exposure**

| | |
|--------------|--|
| Inhalation | No adverse effects due to inhalation are expected. |
| Skin contact | No adverse effects due to skin contact are expected. |
| Eye contact | Direct contact with eyes may cause temporary irritation. |

| | |
|---|---|
| Ingestion | Expected to be a low ingestion hazard. |
| Symptoms related to the physical, chemical and toxicological characteristics | Direct contact with eyes may cause temporary irritation. Ingestion of a large quantity may cause nausea and systemic effects. |
| Information on toxicological effects | |
| Acute toxicity | Not expected to be acutely toxic. |
| Skin corrosion/irritation | Prolonged skin contact may cause temporary irritation. |
| Serious eye damage/eye irritation | Direct contact with eyes may cause temporary irritation. |
| Respiratory or skin sensitization | |
| Respiratory sensitization | Not a respiratory sensitizer. |
| Skin sensitization | This product is not expected to cause skin sensitization. |
| Germ cell mutagenicity | No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. |
| Carcinogenicity | This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. |
| IARC Monographs. Overall Evaluation of Carcinogenicity | |
| Not listed. | |
| NTP Report on Carcinogens | |
| Not listed. | |
| OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053) | |
| Not regulated. | |
| Reproductive toxicity | This product is not expected to cause reproductive or developmental effects. |
| Specific target organ toxicity - single exposure | Not classified. |
| Specific target organ toxicity - repeated exposure | Not classified. |
| Aspiration hazard | Not an aspiration hazard. |
| Chronic effects | Possible hyper sensitization (development of abnormal sensitivity). |

12. Ecological information

| | |
|--------------------------------------|--|
| Ecotoxicity | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. |
| Persistence and degradability | No data is available on the degradability of this product. |
| Bioaccumulative potential | No data available. |
| Mobility in soil | No data available. |
| Other adverse effects | No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component. |

13. Disposal considerations

| | |
|--|--|
| Disposal instructions | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. |
| Local disposal regulations | Dispose in accordance with all applicable regulations. |
| Hazardous waste code | The waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| Waste from residues / unused products | Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| Contaminated packaging | Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied. |

14. Transport information

| | |
|-------------|-----------------------------------|
| DOT | Not regulated as dangerous goods. |
| IATA | Not regulated as dangerous goods. |

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations One or more components are not listed on TSCA. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|----------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|---|------------------------|
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | Yes |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

| | |
|---------------------|--|
| Issue date | 27-April-2015 |
| Revision date | 15-May-2018 |
| Version # | 02 |
| Further information | Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the American Coatings Association (ACA). |
| HMIS® ratings | Health: 1 Flammability: 1 Physical hazard: 0 |

NFPA ratings



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SAFETY DATA SHEET

1. Identification

| | |
|---|---|
| Product identifier | Metacam® (meloxicam) 1.5 mg/mL Oral Suspension for Dogs |
| Other means of identification | None. |
| Recommended use | For the control of pain and inflammation associated with osteoarthritis in dogs. |
| Recommended restrictions | None known. |
| Manufacturer/Importer/Supplier/Distributor information | |
| Manufacturer | Boehringer Ingelheim Vetmedica, Inc. |
| Address | 2621 North Belt Hwy St. Joseph, MO 64506-2002 |
| Transportation emergency | For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident Call CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 Outside USA and Canada: +1 703-527-3887 (collect calls accepted) |
| Medical Emergency (24HR): | (866)638-2226 |
| Non-Emergency calls: | (800) 821-7467 |

2. Hazard(s) identification

| | |
|--|--|
| Physical hazards | Not classified. |
| Health hazards | Not classified. |
| OSHA defined hazards | Not classified. |
| Label elements | |
| Hazard symbol | None. |
| Signal word | None. |
| Hazard statement | The mixture does not meet the criteria for classification. |
| Precautionary statement | |
| Prevention | Observe good industrial hygiene practices. |
| Response | Wash hands after handling. |
| Storage | Store away from incompatible materials. |
| Disposal | Dispose of waste and residues in accordance with local authority requirements. |
| Hazard(s) not otherwise classified (HNOC) | None known. |
| Supplemental information | None. |

3. Composition/information on ingredients

Mixtures

| Chemical name | CAS number | % |
|---------------|------------|----|
| Meloxicam | 71125-38-7 | <1 |

4. First-aid measures

| | |
|---|---|
| Inhalation | If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist. |
| Skin contact | Rinse skin with water/shower. Get medical attention if irritation develops and persists. |
| Eye contact | Rinse with water. Get medical attention if irritation develops and persists. |
| Ingestion | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. |
| Most important symptoms/effects, acute and delayed | Direct contact with eyes may cause temporary irritation. Ingestion of a large quantity may cause nausea and systemic effects. |

| | |
|---|--|
| Indication of immediate medical attention and special treatment needed | Not for human use. For use in animals only. Treat symptomatically. Persons developing anaphylactic (life threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention. |
| General information | Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. |
| 5. Fire-fighting measures | |
| Suitable extinguishing media | Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). |
| Unsuitable extinguishing media | None known. |
| Specific hazards arising from the chemical | During fire, gases hazardous to health may be formed. Combustion products may include: carbon oxides, nitrogen oxides. |
| Special protective equipment and precautions for firefighters | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| Fire fighting equipment/instructions | Move containers from fire area if you can do so without risk. |
| Specific methods | Use standard firefighting procedures and consider the hazards of other involved materials. |
| General fire hazards | No unusual fire or explosion hazards noted. |
| 6. Accidental release measures | |
| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. For personal protection, see section 8 of the SDS. |
| Methods and materials for containment and cleaning up | Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. |
| | Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. |
| | Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. |
| Environmental precautions | Avoid discharge into drains, water courses or onto the ground. |
| 7. Handling and storage | |
| Precautions for safe handling | Avoid prolonged exposure. Use care in handling/storage. |
| Conditions for safe storage, including any incompatibilities | Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Store away from foodstuffs. Store material between 15°C (59°F) and 30°C (86°F). |
| 8. Exposure controls/personal protection | |
| Occupational exposure limits | No exposure limits noted for ingredient(s). |
| Biological limit values | No biological exposure limits noted for the ingredient(s). |
| Appropriate engineering controls | Good general ventilation 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. |
| Individual protection measures, such as personal protective equipment | |
| Eye/face protection | Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear safety glasses with side shields (or goggles). |
| Skin protection | |
| Hand protection | Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear suitable gloves. |
| Other | Not generally required when handling containers. If containers are compromised or exposure to the mixture is likely: Wear lab coat, apron or appropriate clothing to prevent skin contact. |
| 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. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Respirator type: NIOSH approved organic vapor respirator. |
| Thermal hazards | Wear appropriate thermal protective clothing, when necessary. |

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties**Appearance**

| | |
|--|------------------------|
| Physical state | Liquid. |
| Form | Liquid suspension |
| Color | Yellowish. |
| Odor | Honey |
| Odor threshold | Not available. |
| pH | 3.5 - 4.5 |
| Melting point/freezing point | Not available. |
| Initial boiling point and boiling range | Not available. |
| Flash point | > 199.9 °F (> 93.3 °C) |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not applicable. |

Upper/lower flammability or explosive limits

| | |
|---------------------------------------|----------------|
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |

| | |
|-------------------------|------------------|
| Vapor pressure | Not available. |
| Vapor density | Not available. |
| Relative density | 1.56 (water = 1) |

Solubility(ies)

| | |
|--|----------------|
| Solubility (water) | Insoluble |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |

Other information

| | |
|-----------------------------|----------------|
| Explosive properties | Not explosive. |
| Oxidizing properties | Not oxidizing. |

10. Stability and reactivity

| | |
|---|---|
| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. |
| Hazardous decomposition products | No hazardous decomposition products are known. |

11. Toxicological information**Information on likely routes of exposure**

| | |
|---------------------|--|
| Inhalation | No adverse effects due to inhalation are expected. |
| Skin contact | No adverse effects due to skin contact are expected. |
| Eye contact | Direct contact with eyes may cause temporary irritation. |

| | |
|---|---|
| Ingestion | Expected to be a low ingestion hazard. |
| Symptoms related to the physical, chemical and toxicological characteristics | Direct contact with eyes may cause temporary irritation. Ingestion of a large quantity may cause nausea and systemic effects. |
| Information on toxicological effects | |
| Acute toxicity | Not expected to be acutely toxic. |
| Skin corrosion/irritation | Prolonged skin contact may cause temporary irritation. |
| Serious eye damage/eye irritation | Direct contact with eyes may cause temporary irritation. |
| Respiratory or skin sensitization | |
| Respiratory sensitization | Not a respiratory sensitizer. |
| Skin sensitization | This product is not expected to cause skin sensitization. |
| Germ cell mutagenicity | No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic. |
| Carcinogenicity | This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. |
| IARC Monographs. Overall Evaluation of Carcinogenicity | |
| Not listed. | |
| NTP Report on Carcinogens | |
| Not listed. | |
| OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053) | |
| Not regulated. | |
| Reproductive toxicity | This product is not expected to cause reproductive or developmental effects. |
| Specific target organ toxicity - single exposure | Not classified. |
| Specific target organ toxicity - repeated exposure | Not classified. |
| Aspiration hazard | Not an aspiration hazard. |
| Chronic effects | Possible hyper sensitization (development of abnormal sensitivity). |

12. Ecological information

| | |
|--------------------------------------|--|
| Ecotoxicity | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. |
| Persistence and degradability | No data is available on the degradability of this product. |
| Bioaccumulative potential | No data available. |
| Mobility in soil | No data available. |
| Other adverse effects | No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component. |

13. Disposal considerations

| | |
|--|--|
| Disposal instructions | Collect and reclaim or dispose in sealed containers at licensed waste disposal site. |
| Local disposal regulations | Dispose in accordance with all applicable regulations. |
| Hazardous waste code | The waste code should be assigned in discussion between the user, the producer and the waste disposal company. |
| Waste from residues / unused products | Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| Contaminated packaging | Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied. |

14. Transport information

| | |
|-------------|-----------------------------------|
| DOT | Not regulated as dangerous goods. |
| IATA | Not regulated as dangerous goods. |

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations One or more components are not listed on TSCA. Therefore, it can only be used for TSCA exempt purposes such as R&D or veterinary use. FEDERAL LAW RESTRICTS THIS DRUG TO USE BY OR ON ORDER OF LICENSED VETERINARIANS.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|----------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | No |
| Canada | Domestic Substances List (DSL) | No |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | No |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |

| Country(s) or region | Inventory name | On inventory (yes/no)* |
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| New Zealand | New Zealand Inventory | Yes |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | No |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

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| Issue date | 27-April-2015 |
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| Further information | Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the American Coatings Association (ACA). |
| HMIS® ratings | Health: 1 Flammability: 1 Physical hazard: 0 |
| NFPA ratings | |



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