SAFETY DATA SHEETS

This SDS packet was issued with item:

078919200

N/A

Bimeda

PRODUCT INFORMATION

Prxylamax®

Xylazine Injection 100 mg/mL

Sterile

Sedative and Analgesic for Horses

DIN 00805475

INDICATIONS

Horses: Xylamax (xylazine HCl) injection should be used when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia. It has been successfully used when conducting various diagnostic , orthopedic and dental procedures and for minor surgical procedures of short duration. It may also be used as a preanesthetic to local or general anesthesia.

DESCRIPTION

- Xylazine sedative and analgesic for horses.
- Smooth, dependable induction of sedation fr diagnostic, orthopaedic, dental and minor surgical procedures.
- Excellent for use as a pre-anaesthetic to local or general anaesthesia resulting in smooth recoveries.
- Bioequivalent to innovators product.
- Produces calmness and muscle relaxation.
- Wide margin of safety.
- Choice of route of administration; either I.M. or I.V.

PACKAGING

ITEM NO.	UNIT PACKAGE	CASE SIZE
1XYL002	50 mL	12

See reverse side for Administration and Dosage.

Bimeda - MTC Animal Health, Inc. • Beaverdale Road, Cambridge, Ontario N3C2W4
Tel.: (519) 654-8000 / Fax.: (519) 654-8001 / sales@bimedamtc.com / www.bimedamtc.com

Prxylamax®

Xylazine Injection 100 mg/mL

Sterile

Sedative and Analgesic for Horses

DIN 00805475

Veterinary Use Only

DESCRIPTION:
Xylamax (Xylazine HCl) Injection is a clear, colourless solution for intravenous or intramuscular administration supplied in 50 mL multiple-dose vials as a sterile solution.

ACTIVE INGREDIENT:
Xylazine HCl equivalent to 100 mg/mL xylazine base.
Preservatives: 0.9 mg/mL methylparaben and 0.1 mg/mL propylparaben.

ACTIONS:
Xylazine HCl is pharmacologically classified as a non-narcotic sedative with strong analgesic and hypnotic properties.[1 2 3 4] Xylazine HCl produces muscle relaxation by inhibiting the intraneural transmission of impulse in the central nervous system. [1 4]
The drug produces sedation primarily through activation of alpha-adrenergic receptors in the locus coeruleus of the brain to prevent the release of norepinephrine and can be reversed with an alpha 2 adrenergic antagonist such as yohimbine. [5]
Deep sedation develops in the animal within 10 to 15 minutes after intramuscular injection and within 3 to 5 minutes following intravenous administration. [1 2 4 6 7] Deep sedation lasts 15 to 20 minutes, while a sleep-like state, the depth of which is dose-dependent, is usually maintained for 1 to 2 hours following intramuscular administration of the drug at the recommended dosage. [1 2 4 6 7]

Recovery is complete within 30-40 minutes following intravenous injection. [1 2 6 7] In either case, the analgesia lasts from 15-30 minutes. [1 2 4]

In animals under the influence of Xylazine HCl, the respiratory and pulse rates are reduced as in a natural sleep. [1 3 4 5] The intramuscular injection of Xylamax (Xylazine HCl) produces only negligible effects on the cardiovascular and respiratory systems. However, intravenous administration produces significant reductions in tidal volume and respiratory rate in the horse and pony although arterial oxygen and carbon dioxide levels are not appreciably altered. Xylamax (Xylazine HCl) may produce bradycardia which is severe enough to require treatment with an anticholinergic agent (atropine, glycopyrrolate) on rare occasions. Sinoatrial arrest, first, second and third degree A-V blocks and premature ventricular contractions have been observed. Arrhythmias may persist for up to three hours. [1 3 4 5 6] 7 The cardiovascular system of the horse sedated with Xylazine HCl may not respond to stimulation (stress, hemorrhage) with an increased heart and cardiac output like a “normal horse”. [6] Xylazine HCl has no effect on blood clotting time or other hematologic parameters. [4]

INDICATIONS:
Horses- Xylamax (xylazine HCl) injection should be used when it is desirable to produce a state of sedation accompanied by a shorter period of analgesia. It has been successfully used when conducting various diagnostic , orthopedic and dental procedures and for minor surgical procedures of short duration. It may also be used as a preanesthetic to local or general anesthesia.

DOSAGE AND ADMINISTRATION:
Horses- For intravenous or intramuscular administration.
SEDATION AND ANALGESIA- The recommended dosage for intravenous administration is 0.5 mL/45 kg body weight (equivalent to 1.1 mg/kg or 0.5 mg/lb). The recommended dosage for intramuscular administration is 1.0 mL/45 kg body weight (equivalent to 2.2 mg/kg or 1.0 mg/lb).
Following the administration of Xylamax (Xylazine HCl) Injection, the animal should be allowed to rest quietly until the full effect has been reached. These dosages produce a state of sedation which is usually maintained for 1 to 2 hours and analgesia which lasts for 15 to 30 minutes.

PREANESTHETIC TO LOCAL ANESTHESIA- At the recommended dosage rates, Xylamax (Xylazine HCl) Injection may be used in conjunction with local anesthetics, such as procaine and lidocaine.

PREANESTHETIC TO GENERAL ANESTHESIA- At the recommended dosage rates, Xylamax (Xylazine HCl) Injection produces an **additive effect to central nervous system depressants**, such as sodium pentobarbital, sodium thiopental and sodium thiamylal. Accordingly, the dosage of such compounds should be reduced and administered to the desired effect. Generally, 1/3 to 1/2 of the calculated dosage of barbiturates will be needed to produce a surgical plane of anesthesia. Postanesthetic or emergence excitement has not been observed in animals preanesthetized with Xylazine HCl injection.

Xylamax (Xylazine HCl) Injection has been successfully used as a preanesthetic agent with a dose range of 0.3 to 0.6 mg/kg prior to sodium pentobarbital, sodium thiopental, sodium thiamylal, nitrous oxide, ether, halothane, glyceryl guaiacolate or methoxyflurane anesthesia. Xylamax can can be used at full intravenous sedative dose (1.0 to 1.1 mg/kg) before ketamine HCl (Ketalean) induction.

(cont. next page)

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XylaMed 100mg/mL Injection (Xylazine Injection)

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 12/01/2015 Date of issue: 11/17/2015 Version: 1.1

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: XylaMed 100mg/mL Injection (Xylazine Injection)

1.2. Intended Use of the Product

Use of the substance/mixture: Veterinary Sedative & Analgesic.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Bimeda Inc.
One Tower Lane
Oakbrook Terrace Tower
Oakbrook Terrace, IL 60181
T 630-928-0361
F 630-928 0362
www.bimedaus.com

1.4. Emergency Telephone Number

Emergency Number : 519-654-8055, 800-424-9300 CHEMTREC (in US); +1 703-527-3887 CHEMTREC (International and Maritime)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Acute Tox. 4 (Oral)	H302
Skin Irrit. 2	H315
Eye Irrit. 2A	H319

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :

GHS07

Signal Word (GHS-US) : Warning

Hazard Statements (GHS-US) : H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.

Precautionary Statements (GHS-US) : P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves, protective clothing, and eye protection.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 - Specific treatment (see section 4 on this SDS).
P330 - Rinse mouth.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Water	(CAS No) 7732-18-5	87.73	Not classified
Xylazine hydrochloride: 5,6-Dihydro-2-(2,6-xylidino)-4H-1,3-thiazine monohydrochloride	(CAS No) 23076-35-9	11.67	Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335
Trisodium citrate dihydrate	(CAS No) 6132-04-3	0.42	Comb. Dust
Methylparaben	(CAS No) 99-76-3	0.09	Comb. Dust Aquatic Chronic 3, H412
Citric acid	(CAS No) 77-92-9	0.08	Comb. Dust Eye Irrit. 2A, H319
Propylparaben	(CAS No) 94-13-3	0.01	Comb. Dust Aquatic Acute 2, H401

The specific chemical identity and/or exact percentage of composition have been withheld as a trade secret in accordance with Paragraph 1910.1200 of Title 29 of the Code of Federal Regulations.

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

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

Symptoms/Injuries: Causes serious eye irritation. Causes skin irritation. Harmful if swallowed.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid breathing (vapor, mist, spray). Avoid all contact with skin, eyes, or clothing.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Ventilate area. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Heading 8. Exposure controls and personal protection. See Section 13, Disposal Considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, spray. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Products: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Veterinary Sedative & Analgesic.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Protective clothing. Protective goggles.

Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear protective gloves.

Eye Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear liquid
Odor	: No data available
Odor Threshold	: No data available
pH	: 5.2 - 5.8
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: > 93.333 °C (200 °F)
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products: Carbon oxides (CO, CO_2).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Oral: Harmful if swallowed.

XylaMed 100mg/mL Injection (Xylazine Injection)	
ATE (Oral)	1,000.00 mg/kg body weight

Xylazine hydrochloride: 5,6-Dihydro-2-(2,6-xylidino)-4H-1,3-thiazine monohydrochloride (23076-35-9)	
ATE (Oral)	100.00 mg/kg body weight

Methylparaben (99-76-3)	
LD50 Oral Rat	2100 mg/kg

Propylparaben (94-13-3)	
LD50 Oral Rat	> 5000 mg/kg

Citric acid (77-92-9)	
LD50 Oral Rat	5400 mg/kg
LD50 Dermal Rat	> 2000 mg/kg

Skin Corrosion/Irritation: Causes skin irritation.

pH: 5.2 - 5.8

Serious Eye Damage/Irritation: Causes serious eye irritation.

pH: 5.2 - 5.8

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Methylparaben (99-76-3)	
LC50 Fish 1	59.5 mg/l (Exposure time: 96 h - Species: Oryzias latipes)
EC50 Daphnia 1	11.2 mg/l
ErC50 (algae)	91 mg/l
NOEC chronic crustacea	0.2 mg/l (Species: Daphnia magna)
NOEC chronic algae	20 mg/l

Propylparaben (94-13-3)	
LC50 Fish 1	4.1 (4.1 - 8.8) mg/l (Exposure time: 96 h - Species: Danio rerio)
EC50 Daphnia 1	7.97 (7.97 - 32.3) mg/l
NOEC chronic algae	2.1 mg/l

Citric acid (77-92-9)	
LC50 Fish 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and Degradability

XylaMed 100mg/mL Injection (Xylazine Injection)	
Persistence and Degradability	Not established.

Methylparaben (99-76-3)	
Persistence and Degradability	Readily biodegradable, according to appropriate OECD test.

Citric acid (77-92-9)	
Persistence and Degradability	Readily biodegradable in water.

12.3. Bioaccumulative Potential

XylaMed 100mg/mL Injection (Xylazine Injection)	
Bioaccumulative Potential	Not established.

Methylparaben (99-76-3)	
Bioconcentration factor (BCF REACH)	6.4
Log Pow	1.98

Citric acid (77-92-9)	
Log Pow	-1.72 (at 20 °C)

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

XylaMed 100mg/mL Injection (Xylazine Injection)	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard

Methylparaben (99-76-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Propylparaben (94-13-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Citric acid (77-92-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard

Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations Neither this product nor its chemical components appear on any US state lists.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date : 12/01/2015

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
Comb. Dust	May form combustible dust concentrations in air
H301	Toxic if swallowed
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)