
SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	Antipam Injection
Product Identifier:	A 5 mg/mL atipamezole injection for the reversal of medetomidine sedation.
Product Code:	504280 (10mL).
Recommended Use:	For parenteral use in reversing and abolishing the effects of medetomidine hydrochloride in dogs and cats.
Restrictions on Use:	For animal treatment only.
Company Identification:	Jurox Pty Limited.
Address:	85 Gardiner Street, Rutherford, NSW 2320, Australia.
Email:	customerservice@jurox.com.au
Customer Centre:	1800 023 312
National Poisons Information Centre:	13 1126 (24 hours)
Emergency Telephone Number:	1800 023 312 (9am – 5pm, Monday to Friday)

Section 2: HAZARDS IDENTIFICATION

Hazard Classifications:	This product has been assessed according to GHS and is classified as non-hazardous.
Signal word:	None
GHS Pictograms:	None
Precautionary statements:	None
Other hazards:	None known.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Atipamezole hydrochloride	104075-48-1	0.5%
Other ingredients determined to be not hazardous	-	To 100%

Section 4: FIRST AID MEASURES

General Information: Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

Inhalation: If fumes or combustion products are inhaled remove from contaminated area. Is unlikely to present an inhalation problem. If respiratory symptoms do occur, remove to fresh air. Lay patient down and keep warm and rested.

Ingestion: Immediately give a glass of water. First aid is not generally required. If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. For advice, contact a doctor or the National Poisons Centre on 13 1126.

Skin: If skin or hair contact occurs: Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

Eye: If eye contact occurs: Wash out immediately with water. If eye irritation persists, get medical advice/attention. Removal of contact lenses should only be undertaken by skilled personnel.

Injection: Treat as for needlestick injury. Wash area well and disinfect. If other symptoms become evident, seek medical advice.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Treat symptomatically. Administration of atipamezole causes transient changes in heart rate and blood pressure. Clinical use of this drug has caused nervousness, excitation, vomiting and diarrhoea. Other potential side effects of alpha antagonists include hypersalivation, diarrhoea, and tremors.

Section 5: FIRE FIGHTING MEASURES

Flash Point: Not flammable. Not combustible.

Hazardous Combustion Products: If involved in a fire, may emit toxic and corrosive fumes.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Protective gloves, boots and breathing apparatus.

HAZCHEM Code: None specified.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: Wear gloves and appropriate protective clothing. For small spills, clean up spilled product immediately and put in a suitable, labelled container for disposal. For large spills, exclude non-essential people from the area and move upwind. Contain and absorb spill with sand, earth, inert material or vermiculite. Put residues in labelled containers for disposal. Prevent spillage from entering drains or water courses and call emergency services.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

Section 7: HANDLING AND STORAGE

Handling: This is a Schedule 4 (Prescription Animal Remedy) product, available only to or through a veterinarian. Handle this product to avoid exposure, taking all recommended precautions. Avoid contact with skin, eyes and inhalation of vapours. Use in a well-ventilated area. Take care to avoid accidental self-injection. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Keep out of reach of children. Store in securely sealed, original containers, below 30°C (room temperature) in a dry, well-ventilated area. Do not freeze. Store away from foodstuffs.

Other Information: Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: No exposure limits have been assigned for this product. Do not handle until all safety precautions have been read and understood.

Engineering Controls: Handle in a well-ventilated area.

Personal Protective Equipment (PPE):

Eye protection: Protective glasses or goggles are recommended when handling this product.

Skin protection: When handling, prevent skin contact by wearing general protective gloves e.g. light weight rubber gloves.

Respiratory protection: Not required for the normal use of this product.

Other: No special equipment is needed when handling small quantities. OTHERWISE overalls, barrier cream and eyewash unit.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colourless liquid, free of particulate matter.	Lower flammability limits:	Not applicable
Odour:	Not available	Vapour Pressure:	Not available
Odour threshold:	Not available	Vapour density:	Not available
pH:	3.9 – 4.9	Relative density:	Not applicable
Melting Point:	Not available	Specific Gravity:	Not available
Boiling Point:	Not available	Solubility in Water:	Soluble
Flash Point:	Not flammable	Partition coefficient:	Not applicable
Evaporation Rate:	Not applicable	Auto-ignition temperature:	Not available
Flammability:	Not applicable	Decomposition temperature:	Not available
Upper flammability limits:	Not applicable	Viscosity:	Not available

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Extreme temperatures.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: No data available.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity:

Ingestion: Significant oral exposure is unlikely. No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route.

Atipamezole hydrochloride : Oral LD₅₀ : 80 mg/kg (rat)

Inhalation: Is unlikely to present an inhalation problem due to the non-volatile nature of the product. This product is not thought to produce adverse health effects or irritation of the respiratory tract. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to cause skin corrosion / irritation.

Serious Eye Damage / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to cause eye damage / irritation. Direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin sensitiser or respiratory sensitiser.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant.

STOT: Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as a specific target organ toxicant after single exposure.

STOT: Repeat exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as a specific target organ toxicant after repeat exposure. However, exposure by all routes should be minimised as a matter of course.

Aspiration Hazard: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

Narcotic Effects: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to have any narcotic effects.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be ecotoxic.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Atipamezole hydrochloride	No data available	No data available	No data available	No data available

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill. Used needles should immediately be placed in a designated and appropriately labelled 'sharps' container.

Container Disposal: Dispose of empty container by wrapping with paper and putting in garbage.

Section 14: TRANSPORT INFORMATION

Dangerous Goods Classification: Not considered a Dangerous Good for land, sea and air transport.

Section 15: REGULATORY INFORMATION

Poison Schedule (SUSMP): S4

APVMA No.: 65929

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16: OTHER INFORMATION

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

Legend:

AICS	Australian Inventory of Chemical Substances.
CAS No.	Chemical Abstracts Service Registry Number.
CCID	Chemical Classification and Information Database
EPA	Environmental Protection Authority Te Mana Rauhi Taiao
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
HSDB	Hazardous Substances Data Bank
LD₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
NOEC	No-observable-effect-concentration.
PPE	Personal Protective Equipment.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
SWA	Safe Work Australia.

References:

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

This version issued: 29 October 2018 and is valid for 5 years from this date.

Supersedes: This SDS supersedes the version issued on 04 March 2014.

Revision History:

Date of Revision	Reason
29 October 2018	Updated sections 1, 2, 4, 6, 7, 8, 10, 11, 12, 13, 14, 15, Legend and References. Added revision history

END OF SDS