

SAFETY DATA SHEET
PRODUCT: Naloxone Hydrochloride Injection USP

Section 1: PRODUCT AND COMPANY INFORMATION

54/1, Boodhihal village,
Nelamangala,
Bangalore, India-562123.
PRODUCT NAME: Naloxone Hydrochloride Injection USP 0.4 mg/mL

Section 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance	A clear colorless solution, free from visible extraneous matter. Filled in clear tubular glass vial plugged with rubber stopper and sealed with flip off aluminium seal.
Classification of the Substance or Mixture	
Label Elements	
Signal Word:	Not Classified
Hazard Statements:	Not classified in accordance with international standards for workplace safety.
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.	
<i>Potential Health Effects: See Section 11 for more information</i>	
<i>Potential Environmental Effects: See Section 12 for more information</i>	

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Name	CAS Number
Naloxone Hydrochloride	51481-60-8
Sodium Chloride	7647-14-5
Hydrochloric Acid	7647-01-0
Water for injection	-

Section 4: FIRST AID MEASURES

Eye Contact	Flush eye thoroughly with water for at least 15 minutes. If irritation occurs, seek medical attention.
Swallowed	DO NOT induce vomiting. Wash out mouth with water and give plenty of water to drink. Seek medical attention.
Skin contact	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Injection	See prescribing information.
Most Important Symptoms and Effects, Both Acute and Delayed	
Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure:	None known
Indication of the Immediate Medical Attention and Special Treatment Needed	
Aggravated Medical Conditions	Hypersensitivity to Naloxone Hydrochloride or to any of the other ingredients in naloxone hydrochloride injection.
Notes to Physician:	Treat symptomatically.

Section 5: FIRE FIGHTING MEASURES

Fire/Explosion Hazard	Non-combustible. Not considered a significant fire risk. Where possible, contain and collect fire-fighting water for later disposal.
Unsuitable Extinguishing Media:	No restrictions- As for primary cause of fire.
Hazchem Code	None allocated
Specific Hazards Arising from the Chemical:	
Hazardous Combustion Products:	Formation of toxic gases is possible during heating or fire.
Advice for Fire-Fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Personal Protective Equipment and emergency procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
	For personal protection see section 8.
Methods for Cleaning Up:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Environmental Precautions:	Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

Section 7: HANDLING AND STORAGE

Precautions for Safe Handling Hygiene Measures:	Avoid breathing vapour or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for Safe Storage, Including Any Incompatibilities Technical Measures:	Store as directed by product packaging.
Storage Conditions	20°C – 25°C (68°F – 77°F). Protect from light by retaining in carton until ready for use. Discard unused portion
Specific End Use	Pharmaceutical drug product

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Pharmaceutical drug product	No exposure limits set by NOHSC or ACGIH
Engineering Controls	None under normal operating conditions.
Personal Protection	For good infection control, gloves should be worn when administering an injection.
The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.	

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear colourless liquid
Odour	Odourless
Boiling Point/Melting Point	As for water (approx.)
Vapour Pressure	Not determined
Vapour Density	Not determined
Specific Gravity	As for water (approx.)
Flashpoint	Not determined
Flammability Limits	Not determined
Solubility in Water	Aqueous solution.

Section 10: STABILITY AND REACTIVITY

Reactivity:	Not known to be incompatible with other materials.
Chemical Stability:	Stable under recommended storage conditions.
Decomposition Products	Not determined
Possibility of Hazardous Reactions	
Oxidizing Properties:	None
Conditions to Avoid:	Not determined
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide, oxides of nitrogen and hydrogen chloride.

Section 11: TOXICOLOGY INFORMATION

Accidental Injection	May cause allergic reactions, nausea, palpitations, and increased blood pressure.
	Severe allergic reactions will usually occur within the first few hours of exposure. The sooner the onset of an allergic reaction, the more severe the reaction.
Eye	May cause irritation.
Swallowed	May cause allergic reactions or gastro-intestinal upset and increased blood pressure.
Skin	No adverse health effects known.
Inhaled	Not an expected route of exposure.
Chronic Health Effects	No chronic health effects known.
Carcinogen Status:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity
Aquatic: No data available.
Terrestrial: No data available.
Persistence and Degradability: No data available.
Bio accumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

Section 13: DISPOSAL CONDITIONS

Waste Disposal:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

Section 14: TRANSPORTATION INFORMATION

UN Number None allocated

DG Class None allocated

Subsidiary Risk None allocated

Packing Group None allocated

Hazchem Code None allocated

The following refers to all modes of transportation unless specified below.

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

Section 15: REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

Section 16: OTHER INFORMATION

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