INTERNATIONAL MEDICATION SYSTEMS, LIMITED
1886 SANTA ANITA AVENUE, SOUTH EL MONTE, CALIFORNIA 91733
AREA CODE (800) 423-4136, (909) 980-9484 (INTERNATIONAL)
FAX (626) 459-5255

MATERIAL SAFETY DATA SHEET

SECTION I. IDENTIFICATION	
Identity/Material Name	Naloxone Hydrochloride Injection USP, 1 mg/mL (contains no preservative)
Synonyms	(-)-17-Allyl-4,5α-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride
Stock Number	1469, 3369
NDC Number	76329-1469-5 76329-1469-1 76329-3369-1
Unit Size	1469: 2 mg/ 2 mL (single dose disposable MIN-I-JET® prefilled syringe) 3369: 2 mg/ 2 mL (single dose disposable Luer-Jet™ prefilled syringe)
Intended Use	Rx Only. Naloxone hydrochloride injection is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids including, propoxyphene, methadone and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine and butorphanol and cyclazocine. Naloxone hydrochloride is also indicated for the diagnosis of suspected or known acute opioid overdosage. Naloxone hydrochloride injection may be useful as an adjunctive agent to increase blood pressure in the management of septic shock.
Company Information	
Manufacture	International Medication Systems, Limited (IMS) 1886 Santa Anita Avenue, South El Monte, California 91733 Tel (800) 423-4136 Fax (626) 459-5255
Emergency Number	(800) 423-4136 (US Domestic), (909) 980-9484 (International)
SECTION II. HAZARD(S) IDENTIFICATION	
Emergency Overview	Clear, colorless Liquid Odor unknown Naloxone hydrochloride should be administered cautiously to persons including newborns of mothers who are known or suspected to be physically dependent on opioids. In such cases an abrupt and complete reversal of opioid effects may precipitate an acute withdrawal syndrome.
Statement of Hazard	Excessive doses of naloxone hydrochloride in postoperative patients may result in significant reversal of analgesia and may cause agitation.

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Potential Health Effect	The following adverse events have been associated with the use of naloxone hydrochloride in postoperative patients: hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in postoperative patients may result in significant reversal of analgesia and may cause agitation. Adverse events associated with the postoperative use of naloxone hydrochloride include disorders of the cardiac, gastrointestinal, nervous system, psychiatric, respiratory, skin and subcutaneous tissue or vascular.	
Hazard Class	Not available	
Hazard Category	GHS Classification	Unknown
	Classification according to EC Directive 1272/2008	Acute Tox. 4 (H302)
	Classification according to EC Directives 64/548/EEC (substances) or 1999/45/EC (mixtures)	R22
SECTION III. COMPOSITION/INFORMATION ON INGREDIENTS		
Active Ingredient	Naloxone HCl Dihydrate USP	
	Approximate % by weight: 0.04	RTECS No. QD2275000
	EC Number: 206-611-0	CAS #: 357-08-4
Inactive Ingredients	Sodium Chloride Hydrochloric Acid NF (0.01N) Water for Injection USP	
Chemical Formula	$C_{19}H_{21}NO_4 \bullet HCl$	
SECTION IV. FIRST-AID MEASURES		
Eye Contact	Flush eyes immediately with copious amounts of water or normal saline solution for at least 15 minutes. Seek medical attention if deemed necessary.	
Skin Contact	Immediately flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. Seek medical attention if warranted.	
Inhalation	Remove from source of exposure. Seek medical attention if needed or if signs of toxicity occur.	
Ingestion	Remove from source of exposure. Seek medical attention if needed or if signs of toxicity occur.	

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Effect and Treatment of Overdosage	There is no clinical experience with naloxone hydrochloride overdosage in humans. **Adult Patients** In one small study, volunteers who received 24 mg/70 kg did not demonstrate toxicity. In another study, 36 patients with acute stroke received a loading dose of 4 mg/kg (10 mg/m2/min) of naloxone hydrochloride followed immediately by 2 mg/kg/hr for 24 hours. Twenty-three patients experienced adverse events associated with naloxone use, and naloxone was discontinued in seven patients because of adverse effects. The most serious adverse events were: seizures (2 patients), severe hypertension (1), and hypotension and/or bradycardia (3). At doses of 2 mg/kg in normal subjects, cognitive impairment and behavioral symptoms, including irritability, anxiety, tension, suspiciousness, sadness, difficulty concentrating, and lack of appetite have been reported. In addition, somatic symptoms, including dizziness, heaviness, sweating, nausea, and stomachaches were also reported. Although complete information is not available, behavioral symptoms were reported to often persist for 2-3 days. **Pediatric Patients** Up to 11 doses of 0.2 mg of naloxone (2.2 mg) have been administered to children following overdose of diphenoxylate hydrochloride with atropine sulfate. Pediatric reports include a 2-1/2 year-old child who inadvertently received a dose of 20 mg of naloxone for treatment of respiratory depression following overdose with diphenoxylate hydrochloride with atropine sulfate. The child responded well and and recovered without adverse sequelae. There is also a report of a 4-1/2 year-old child who received 11 doses during a 12-hour period, with no adverse sequelae. **Patient Management** Patients who experience a naloxone hydrochloride overdose should be treated symptomatically in a closely supervised environment. Physicians should contact a poison control center for the most up-to-date patient management information.

SECTION V. FIRE-FIGHTING MEASURES		
Extinguishing Media		Water, carbon dioxide, dry chemical or foam.
Special Fire-Fighting Precautions		No special precautions determined for this product.
Flammability		
Fire/Explosion Hazards		None anticipated for this product.
Hazardous Combustion Products		Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx) and hydrogen chloride.
Flash Point		Unknown
Auto-Ignition Temperature		Not Applicable
Flammable Limits	LEL	Not Applicable
	UEL	Not Applicable

SECTION VI. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Avoid generation of dust during clean-up. Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Steps to be Taken if Released or Spilled	Use absorbent paper to pick up all liquid spill material. Seal the absorbent paper, as well as contaminated clothing, in a vapor-tight plastic bag for eventual disposal. Wash spill site with a soap and copious amounts of water.
SECTION VII. HANDLING AND STORAGE	
Handling	No special handling required under conditions of normal product use. Improper engaging of vial and injector may cause glass breakage and subsequent injury.
Storage	Naloxone hydrochloride injections should be stored at 15 – 30 °C and protected from light.
SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION	
Exposure Limits	Not applicable
Personal Protective Equipment (PPE)	
Eye Protection	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.
Skin Protection	Adequate skin protection recommended including gloves. Lab coats or additional precaution may be required based on procedure or level of exposure. Consult your site safety staff for guidance.
Respiratory Protection	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Engineering Controls	The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.
SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES	
Appearance and Odor	Clear, colorless solution
Physical State	Liquid

pH	3.5± 0.5
Melting Point(°C)	Not Applicable
Freezing Point(°C)	Not Applicable
Boiling Point(°C)	Not Applicable
Evaporation Rate	Water solvent will slowly evaporate
Vapor Pressure	Unknown
Vapor Density	Unknown
Relative Density	Unknown
Solubility(ies)	Soluble in water, in dilute acids, and in strong alkali
Partition coefficient	Unknown
Decomposition Temperature	Unknown
Viscosity	Unknown
Flammability	See **Section V: Fire Fighting Measures** for flammability/explosivity information.

SECTION X. STABILITY AND REACTIVITY

Stability/Reactivity	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined.
Incompatibilities/ Conditions to Avoid	Avoid light and temperatures outside of 15 – 30 °C.
Hazardous Decomposition Products	Not determined
Hazardous Polymerization	Not anticipated to occur with this product.

SECTION XI. TOXICOLOGICAL INFORMATION

The data presented below is for this product or for a structurally similar product.

Acute Toxicity

Test Type	Route of Administration	Value	Units	Species
LD_{50}	Intravenous	150 ± 5	mg/kg	mice
LD_{50}	Intravenous	109 ± 4	mg/kg	rats
LD_{50}	Subcutaneous	260 (228 – 296)	mg/kg	newborn rats

Repeat Dose Toxicity Data

Subchronic/ Chronic Toxicity	Based on clinical use, possible target organs include the central nervous system and cardiovascular system.

Reproductive/ Developmental Toxicity	Pregnancy Category C: Teratology studies conducted in mice and rats at doses 4-times and 8-times, respectively, the dose of a 50 kg human given 10 mg/day (when based on surface area or mg/m2), demonstrated no embryotoxic or teratogenic effects due to naloxone hydrochloride. There are, however, no adequate and well- controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, naloxone hydrochloride should be used during pregnancy only if clearly needed It is not known if naloxone hydrochloride affects the duration of labor and/or delivery. However, published reports indicated that administration of naloxone during labor did not adversely affect maternal or neonatal status. It is not known whether naloxone is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when naloxone is administered to a nursing woman.
Mutagenicity/Genotoxicity	Naloxone hydrochloride was weakly positive in the Ames mutagenicity and in the *in vitro* human lymphocyte chromosome aberration test but was negative in the *in vitro* Chinese hamster V79 cell HGPRT mutagenicity assay and in the *in vivo* rat bone marrow chromosome aberration study.
Carcinogenicity	Studies in animals to assess the carcinogenic potential of naloxone hydrochloride have not been conducted.

SECTION XII. ECOLOGICAL INFORMATION	
Ecotoxicity Data	Not determined for this product
Environmental Data	Not determined for this product
SECTION XIII. DISPOSAL CONSIDERATIONS	
Method of Disposal	Approved chemical waste incineration or approved aqueous discharge to municipal or on-site wastewater treatment systems.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.
SECTION XIV. TRANSPORT INFORMATION	
This material is not subject to the transportation regulations of USDOT, EUADR, IATA, or IMDG/IMO	
SECTION XV. REGULATORY INFORMATION	
US State Regulations	Check state requirements for ingredient listing.
RCRA Status	Not listed
U.S. OSHA Classification	Target Organ Toxin Possible Irritant
TSCA Listing	Not listed
GHS Classification	Unknown
Symbol	Not applicable
Response	See First Aid measures **(Section IV)**

SECTION XVI. OTHER INFORMATION	
Pharmaceutical Use	This product is Rx Only. Please follow instructions in the package insert.
Abbreviations	
ADR	Agreement on Dangerous Goods by Road
CAS	Chemical Abstracts Service Number
DOT	US Department of Transportation Regulations
IATA	International Air Transport Association
IMDG/IMO	International Maritime Dangerous Goods Code/International Maritime Organization
LD50	Dosage producing 50% mortality
LEL	Lower Exposure Limit
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
TSCA	Toxic Substance Control Act
UEL	Upper Exposure Limit
Revision Date	07/10/14
Supersedes Date	10/11/13

Rx Only. Refer to package insert for additional information.

The information contained herein is believed to be complete and accurate. However, it is the user's responsibility to determine the suitability of the information for their particular purpose. The company assumes no additional liability or responsibility resulting from the usage of, or reliance on this information.

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