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INTERNATIONAL MEDICATION SYSTEMS, LIMITED
 1886 SANTA ANITA AVENUE, SOUTH EL MONTE, CALIFORNIA 91733
 AREA CODE (800) 423-4138 FAX (626) 459-5255

MATERIAL SAFETY DATA SHEET

SECTION I - IDENTIFICATION INFORMATION			
Identity/Material Name: Naloxone Hydrochloride Injection USP, 1 mg/mL (contains no preservative)			
Stock Number: 3369			
NDC Number: 0548-3369-00			
Unit Size: 2 mg/ 2 mL (single dose disposable Luer-Jet™ prefilled syringe)			
Manufacturer Name: International Medication Systems, Limited (IMS)		Telephone:	(800)423-4136
Address: 1886 Santa Anita Avenue, South El Monte, California 91733		Fax:	(626)459-5255
SECTION II - HAZARDOUS INGREDIENTS IDENTIFICATION INFORMATION			
Ingredient Name:	Amount per mL:	Permissible Exposure Level:	
Naloxone HCl Dihydrate USP	1.1 mg	Unknown	
Sodium Chloride	8.35 mg	Unknown	
Hydrochloric Acid NF (0.01N)	As needed to adjust pH	Unknown	
Water for Injection USP	QS Ad	N/A	
SECTION III - PHYSICAL CHEMICAL DATA			
Boiling Point (°C):	Unknown	Melting Point (°C):	N/A
Viscosity:	Unknown	Vapor Pressure:	Unknown
Specific Gravity:	N/A	Percentage Volatile:	N/A
Vapor Density:	Unknown	Evaporation:	Water solvent will slowly evaporate
Solubility in Water:	Miscible in water and alcohol.		
Appearance and Odor:	Clear, colorless solution.		
SECTION IV - FIRE AND EXPLOSION DATA			
Flash Point:	Unknown	Flammable Limits: LEL:	N/A
		UEL:	N/A
Extinguishing Media:	Water, carbon dioxide, dry chemical or foam.		
Special Fire Procedures:	Unknown		
Approved By: QA/ <i>[Signature]</i>	Date Prepared: 5-15-01		

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SECTION V - REACTIVITY DATA

Stability:	Naloxone hydrochloride injections should be stored at 15 -- 30 °C and protected from light. The pH of solution is adjusted with Hydrochloride to meet USP limit of 3 to 4.5.
Conditions to Avoid:	Temperature outside of 15°C to 30°C. Light exposure.
Compatibility:	Naloxone hydrochloride injection should not be mixed with preparations containing bisulfite, metabisulfite, long-chain or high molecular weight anions, or any solution having an alkaline pH. Drugs or chemical agents should not be added to solutions of naloxone hydrochloride unless their effect on the chemical and physical stability of the solution has been established. Specialized references should be consulted for specific compatibility information.

Hazardous Decomposition Products: Unknown

SECTION VI - TOXICOLOGICAL DATA

LD ₅₀ :	Intravenous: 150 ± 5 mg/kg in mice 109 ± 4 mg/kg in rats subcutaneous: 260 (228 -- 296) mg/kg in newborn rats
Carcinogenesis, Mutagenesis, Impairment of Fertility, Pregnancy, and Lactation:	Carcinogenicity and mutagenicity studies have not been performed with naloxone hydrochloride. Reproductive studies in mice and rats demonstrated no impairment of fertility. Pregnancy Category B. Reproduction studies performed in mice and rats at doses up to 1,000 times the human dose revealed no evidence of impaired fertility or harm to the fetus due to naloxone. 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 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.
Symptoms and Treatment of Overdosage:	There is no clinical experience with naloxone hydrochloride overdosage in humans. In the mouse and rat the intravenous LD ₅₀ is 150 ± 5 mg/kg and 109 ± 4 mg/kg respectively. In acute subcutaneous toxicity studies in newborn rats the LD ₅₀ (95% CI) is 260 (228 -- 296) mg/kg. Subcutaneous injection of 100 mg/kg/day in rats for 3 weeks produced only transient salivation and partial ptosis following injection: no toxic effects were seen at 10 mg/kg/day for 3 weeks.
Eye Contacts:	Flush eyes immediately with copious amounts of water or normal saline solution for at least 15 minutes. Seek medical attention if deemed necessary.
Skin Irritation:	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.

Approved By: OA/ Diana Jant Date Prepared: 5-15-01

MATERIAL SAFETY DATA SHEET

SECTION VI - HEALTH HAZARD DATA (CONTINUED)

Inhalation: Remove victim to fresh air. Give oxygen or artificial respiration, if necessary.

Accidental Ingestion: Do not induce vomiting. Seek physician's care.

Systemic:

Naloxone Hydrochloride Injection is available as a preserved or non-preserved sterile solution for intravenous, intramuscular or subcutaneous administration.

Naloxone hydrochloride prevents or reverses the effects of opioids, including respiratory depression, sedation, and hypotension. Also, it can reverse the psychotomimetic and dysphoric effects of agonist-antagonist such as pentazocine.

Naloxone hydrochloride is an essentially pure narcotic antagonist, i.e., it does not possess the "agonistic" or morphine-like properties characteristic of other narcotic antagonists; naloxone does not produce respiratory depression, psychotomimetic effects or pupillary constriction. In the absence of narcotics or agonistic effects of other narcotic antagonists, it exhibits essentially no pharmacologic activity.

Naloxone has not been shown to produce tolerance nor to cause physical or psychological dependence. In the presence of physical dependence on narcotics, naloxone will produce withdrawal symptoms.

While the mechanism of action of naloxone is not fully understood, the preponderance of evidence suggests that naloxone antagonizes the opioid effects by competing for the same receptor sites. When naloxone hydrochloride is administered intravenously the onset of action is generally apparent within two minutes; the onset of action is only slightly less rapid when it is administered subcutaneously or intramuscularly. Intramuscular administration produces a more prolonged effect than intravenous administration. The requirement for repeat doses of naloxone, however, will also be dependent upon the amount, type and route of administration of the narcotic being antagonized.

Following parenteral administration naloxone hydrochloride is rapidly distributed in the body. It is metabolized in the liver, primarily by glucuronide conjugation, and excreted in urine. In one study the serum half-life in adults ranged from 30 to 81 minutes (mean 64 ± 12 minutes). In a neonatal study, the mean plasma half-life was observed to be 3.1 ± 0.5 hours.

Abrupt reversal of narcotic depression may result in nausea, vomiting, sweating, tachycardia, increased blood pressure, tremulousness, seizures and cardiac arrest. In postoperative patients, larger than necessary dosages of naloxone hydrochloride may result in significant reversal of analgesia, and in excitement. Hypotension, hypertension, ventricular tachycardia and fibrillation, and pulmonary edema have been associated with the use of naloxone postoperatively.

Naloxone hydrochloride injection is contraindicated in patients known to be hypersensitive to it. 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 narcotic effects may precipitate an acute abstinence syndrome.

The patient who has satisfactorily responded to naloxone should be kept under continued surveillance and repeated doses of naloxone should be administered, as necessary, since the duration of action of some narcotics may exceed that of naloxone.

Approved By: OAI Diane J. S. Date Prepared: 5-15-01

MATERIAL SAFETY DATA SHEET

SECTION I - IDENTIFICATION (CONTINUED)	
Systemic (Continued)	<p>Naloxone is not effective against respiratory depression due to non-opioid drugs. Reversal of buprenorphine-induced respiratory depression may be incomplete. If an incomplete response occurs, respirations should be mechanically assisted.</p> <p>In addition to naloxone, other resuscitative measures such as maintenance of a free airway, artificial ventilation, cardio massage, and vasopressor agents should be available and employed when necessary to counteract acute narcotic poisoning.</p> <p>Several instances of hypotension, hypertension, ventricular tachycardia and fibrillation, and pulmonary edema have been reported. These have occurred in postoperative patients, most of whom had pre-existing cardiovascular disorders or received other drugs which may have similar adverse cardiovascular effects. Although a direct cause-and-effect relationship has not been established, naloxone should be used with caution in patients with pre-existing cardiac disease or patients who have received potentially cardiotoxic drugs.</p>
SECTION II - HAZARD IDENTIFICATION	
Precautions	Improper engaging of vial and injector may cause glass breakage and subsequent injury.
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.
Waste Disposal	Approved chemical waste incineration or approved aqueous discharge to municipal or on-site wastewater treatment systems.
SECTION III - CONTROL MEASURES	
Respiratory Protection	N/A
Ventilation	Local ventilation adequate.
Skin Protection	Adequate skin protection recommended including gloves.
Eye Protection	Adequate eye protection recommended including safety glasses.
Approved By: <u>OAK [Signature]</u>	Date Prepared: <u>5-15-01</u>

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. International Medication Systems, Limited assumes no additional liability or responsibility resulting from the usage of, or reliance on this information.