# NALOXONE HYDROCHLORIDE

<table>
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<th>PRODUCT</th>
<th>DELIVERY SYSTEM</th>
<th>UNIT SIZE</th>
<th>UNITS / BOX</th>
<th>NDC#</th>
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<tbody>
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<td>Luer-Jet™ Prefilled Syringe</td>
<td>2 mg / 2 mL</td>
<td>10</td>
<td>76329-3369-1</td>
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<tr>
<td>Naloxone HCl Inj., USP [1 mg/mL]</td>
<td>MIN-I-JET® Prefilled Syringe</td>
<td>2 mg / 2 mL</td>
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### WHOLESALER ITEM NUMBERS

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<th>CARDINAL</th>
<th>MCKESSON</th>
<th>MORRIS &amp; DICKSON</th>
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TO PLACE AN ORDER, PLEASE CALL 1-800-423-4136

INTERNATIONAL MEDICATION SYSTEMS, LIMITED
1886 Santa Anita Ave., So. El Monte, CA 91733
An Amphastar Pharmaceuticals Company | www.ims-limited.com

Please see reverse for important safety information, including Warnings and Precautions and Indications and Usage, for Naloxone Hydrochloride Injection, USP.
NALOXONE HYDROCHLORIDE Injection, USP

**DESCRIPTION**

Naloxone hydrochloride, an opioid antagonist, is a synthetic congener of morphine. It differs structurally from the methyl group in the opiate ring of morphine.

**PHARMACOKINETICS**

Parenteral administration is recommended as a suitable route for intravenous, intramuscular or subcutaneous administration in 1-mg/mL concentration. Each mL contains 8.35 mg of sodium chloride. Naloxone Hydrochloride Injection is preservative-free.

**CLINICAL PHARMACOLOGY**

**Concurrent or Partial Opposites of Opioid Depression**

Naloxone hydrochloride prevents or reverses the effects of opioids in respiratory depression, sedation, and hypotension. It can, therefore, reverse the psychomotor depression and the hypotension associated with the use of opioids.

Naloxone hydrochloride is an essentially pure opioid antagonist, i.e., it does not possess the "agonist" or "blocking properties characteristic of other opioid antagonists. When administered intravenously or intramuscularly in sufficient dose, naloxone hydrochloride produces a state of opioid antagonism, with depression of respiratory function and severe systemic vasoconstriction, accompanied by an increase in blood pressure and heart rate. Oral administration of naloxone hydrochloride has not been shown to produce a totolecular or partial-oppositional dependence in the physical or psychological dependence associated with opioids.

Naloxone hydrochloride has not been shown to produce a tolerance partially or complete-oppositional dependence in the physical or psychological dependence associated with opioids. However, in the presence of physical dependence or opioid, naloxone hydrochloride will produce withdrawal symptoms. However, in the presence of physical dependence, opioid withdrawal symptoms may appear even at late stages of maternal opioid withdrawal, naloxone hydrochloride may have no apparent effect on the severity of these symptoms.

Use in Septic Shock

Naloxone hydrochloride injection, USP may be administered intravenously, intramuscularly or subcutaneously in children and neonates to reverse the effects of opioids. Naloxone hydrochloride is well absorbed following intravenous, intramuscular, or subcutaneous injection. The safety and effectiveness of naloxone hydrochloride in patients with renal insufficiency/failure have not been established in well-controlled clinical trials. Caution should be exercised when naloxone hydrochloride is administered to patients with renal impairment.

Adverse Reactions

The safety and effectiveness of naloxone hydrochloride in patients with renal insufficiency/failure have not been established in well-controlled clinical trials. Caution should be exercised when naloxone hydrochloride is administered to patients with renal impairment.

**DOSAGE AND ADMINISTRATION**

**Usage**

Naloxone hydrochloride injection, USP, for intravenous, intramuscular and subcutaneous administration. Available as follows:

**Usage in Adults**

Postoperative Opioid Depression

The initial dose of naloxone hydrochloride should be 0.01 mg/kg body weight administered I.V., I.M., or S.C. This dose may be repeated at two- to three-minute intervals if the response is inadequate. A maximum of 0.2 mg/kg body weight may be given intravenously, intramuscularly, or subcutaneously during the initial 15 to 20 minutes of therapy. If no response is observed after 20 minutes of therapy, it may be repeated at two- to three-minute intervals.

Septic Shock

The initial dose may be 0.4 mg to 2 mg of naloxone hydrochloride injected intravenously. If the desired degree of improvement is not obtained, the dose may be repeated at two- to three-minute intervals. The dose may be titrated to effect.

Vascular Disorders:

The usual initial dose is 0.01 mg/kg body weight administered I.V., I.M., or S.C. This dose may be repeated at two- to three-minute intervals. The dose may be titrated to effect.

Respiratory Depression Due to Other Drugs

The initial dose of naloxone hydrochloride may be 0.005 mg/kg body weight intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenously. If there is no response, an additional dose of 0.01 mg/kg body weight may be given intravenous.