# FIRST TIME GENERIC APPROVAL

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| **Brand Name** | Narcon® |
| **Generic Name** | naloxone hydrochloride |
| **Drug Manufacturer** | Sandoz Inc |

## New Drug Approval

### TYPE OF CLINICAL UPDATE

First Time Generic

### FDA APPROVAL DATE

December 22,2021

### LAUNCH DATE

December 22, 2021

### REVIEW DESIGNATION

New Drug Application (NDA):208411

### TYPE OF REVIEW

N/A

### DISPENSING RESTRICTIONS

N/A

## Overview

### INDICATION FOR USE

- Naloxone HCl Nasal Spray is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
- Naloxone HCl Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.
- Naloxone HCl Nasal Spray is not a substitute for emergency medical care.

### MECHANISMS OF ACTION

Naloxone hydrochloride is an opioid antagonist that antagonizes opioid effects by competing for the same receptor sites. Naloxone hydrochloride reverses the effects of opioids, including respiratory depression, sedation, and hypotension. It can also reverse the psychotomimetic and dysphoric effects of agonist-antagonists such as pentazocine.

### DOSE FORM AND STRENGTH

Nasal spray: 4 mg of naloxone hydrochloride in 0.1 mL.

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## DOSE & ADMINISTRATION

Administration of a single spray of naloxone HCl Nasal Spray intranasally into one nostril and administer additional doses of naloxone HCl Nasal Spray, using a new nasal spray with each dose, if the patient does not respond or responds and then relapses into respiratory depression, additional doses of naloxone HCl Nasal Spray may be given every 2 to 3 minutes until emergency medical assistance arrives.