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NARCAN[®] (naloxone HCl) NASAL SPRAY 4mg

**FOR EMERGENCY TREATMENT
OF OPIOID OVERDOSE**

Please see Indication and Important Safety Information below.

- ✓ 4 mg nasal dose in single spray
- ✓ Ready-to-use
- ✓ Needle-free



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Commercial Availability

NARCAN[®] (naloxone HCl) Nasal Spray 4 mg is scheduled to become commercially available early 2016.

For more information on NARCAN[®] Nasal Spray call 844-4-NARCAN (844-462-7226) or email customerservice@adaptpharma.com

Indications and Important Safety Information

INDICATIONS

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NARCAN[®] Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN[®] Nasal Spray is not a substitute for emergency medical care.

IMPORTANT SAFETY INFORMATION

NARCAN[®] Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal and acute withdrawal syndrome. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for development of opioid withdrawal.

Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were observed in a NARCAN Nasal Spray clinical study: increased blood pressure, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.

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To report SUSPECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. at 1-844-4NARCAN (1-844-462-7226) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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Group Purchasers

NARCAN[®] Nasal Spray will be available to group purchasers, such as law enforcement, firefighters, first responders, departments of health, educational facilities and community based organizations.

For information, pre-ordering or purchasing NARCAN[®] Nasal Spray (NDC: 69547-353-02) upon availability, contact 844-4-NARCAN (844--462-7226) or email customerservice@adaptpharma.com

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Scope

This Privacy Statement applies only to the operation of websites that directly link to this statement when you click on "Privacy Statement" in the website footer.

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Building 4, Suite 201
Radnor, PA 19087

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Reversal of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal and acute withdrawal syndrome. In severe cases, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for development of opioid withdrawal.

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