September 18, 2018

To Whom It May Concern:

This letter identifies Adapt Pharma as the sole manufacturer of NARCAN® (naloxone HCl) Nasal Spray. Upon approval of the product, the following Press Release was issued:

On November 19, 2015 – Adapt Pharma announced that the U.S. Food and Drug Administration (FDA) has approved NARCAN® Nasal Spray for the emergency treatment of known or suspected opioid overdose. NARCAN® Nasal Spray, a ready-to-use, needle-free device, delivers a 4 mg dose of naloxone in a single 0.1 ml nasal spray. NARCAN® Nasal Spray requires no assembly or priming prior to use.

NARCAN® NASAL SPRAY INDICATIONS AND IMPORTANT SAFETY INFORMATION

Indications

NARCAN® (naloxone hydrochloride) 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. 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 characterized by body aches, fever, sweating, runny nose, sneezing, goose bumps (piloerection), yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure and increased heart rate (tachycardia). In some patients, there may be aggressive behavior upon abrupt reversal of an opioid overdose. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may be characterized by convulsions, excessive crying, and hyperactive reflexes. Monitor for the 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, constipation, toothache, muscle spasms, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, nasal inflammation, rhinalgia, and xeroderma.

See Instructions for Use and full prescribing information in the use of this product, available here: http://www.narcan.com/pdf/NARCAN-Prescribing-Information.pdf.

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Additional information, including full prescribing information for NARCAN® Nasal Spray, and important safety information and instructions for use, is also available at www.NARCAN.com.

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.

Sincerely,

Jason Jones

Jason Jones
Vice President - Trade Operations, Pricing, and Contracting