

Commercial Availability

NARCAN® (naloxone HCI) 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

DOCKET

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 and acute withdrawal syndrome. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for development of opioid withdrawal.

<u>Risk of Cardiovascular (CV) Effects</u>: 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.

See Instructions for Use and full prescribing information in the use of this product.

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

Privacy Statement | Terms of Use | Contact Us | Media 🗹

© 2015 ADAPT Pharma, Inc. NARCAN® is a registered trademark licensed to ADAPT Pharma Operations Limited. NAR4-08-15 ADAPT Pharma, Inc. Radnor, PA



LARM Find authenticated court documents without watermarks at docketalarm.com.

| If this is an emergenc | , call 911. This site | is intended for US residen |
|------------------------|-----------------------|----------------------------|
|------------------------|-----------------------|----------------------------|



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

Indications and Important Safety Information

INDICATIONS

DOCKET

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 and acute withdrawal syndrome. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for development of opioid withdrawal.

<u>Risk of Cardiovascular (CV) Effects</u>: 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.

See Instructions for Use and full prescribing information in the use of this product.

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 🗗.

Privacy Statement | Terms of Use | Contact Us | Media 🖉

© 2015 ADAPT Pharma, Inc. NARCAN® is a registered trademark licensed to ADAPT Pharma Operations Limited. NAR4-08-15 ADAPT Pharma. Inc. Radnor. PA



LARM Find authenticated court documents without watermarks at <u>docketalarm.com</u>.



Privacy Statement

Adapt Pharma, Inc. respects the privacy of visitors to our websites, and as a result, we have developed this Online Privacy Statement. We may update this Statement from time to time.

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

vestate footer. CONSENT TO PROCESSING IN THE UNITED STATES AND ELSEWHERE. This site is owned and operated by Adapt Pharma in the United States, but he information you provide may be accessible to our affiliates, vendors and supplies in other countries. By using this site, you consent to the collection, states and processing of your information in the United States and in any country to which we may transfer your information in the course of our business operations.

course of our business operations. Information Routinety Collected by Dur Website Technology Web tog Dat via analytics cookies, Dur websierer will mudinely patient web log data, somatimes from cookies on your computer, when you visit the of our website. The websiter moutantiality intercipties compension if formation such as the date and fine you visited, the he pages you visited, the website you came from, the type of browser and operating system you are using, and the domain name and address of your inferrent service provide. If Address, We record the Internet Proback TP' address of your computer when you visit defenses does and defently you persenting to all is what allows to infinition communitations with your conduct are system one using and the domain name and address of your information perform their site enalytics, Cookies and Other Technologies, We also collect information about your use dour alle through technologies uso has cookies and web beaces. A web beaces will be your computer site to a technologies uso is a built built of the site unalytics, cookies and web boards with your conduct and the tradition and your computer site to most all that relates is a unique numeric code that we transfer to your computer site that we can keep track dyour interests and preferences and recognize you as intum visitor our site. We asse codes with ad lefted (it certatation about to bring you content and features likely to be of interest to you, based or your previous activities on our site.

se a networkshow our alse. We use cookes without directly identifiable personal information to bring you content and features filety to be of internal to you, have do nyour provides advectiles on use at the New You Your Information multimity contents, and to improve our verbates and services. We may enhance on merge this information with the We have information multimity contents, and to improve our verbates and services. We may enhance on merge this information with the data was may be not advected to a service and the service and the services. We may enhance on merge this information with the data was may be not advected to a service and the services. We may enhance on merge this information with the data was may be not advected to a service and the services. We may enhance on merge this information with the data was may be not advected to a service and the services and also may use your IP address to personalize control power do in the vehicle. Hommation nucleive control was and the information contineed in them. The data was the data was been used to be advected to a service and the information contineed in them. We be advected to the vehicle in the service and them metals and regulates the information contineed in them. We be advected to the service and the services and information to controls to contents. Context, Services and deed windring you have contexters, you compatible. It is possible that a contexter and you contained in advected or services that may be of interest to you. We also analyze the information contexter and interest to a service and information and prove the functioning of our sets to monoting interim to acute and and to mark the services and information we proved to the end contexter formand. We use the information advected through the use of contextes in a do mark the services and information to be related and proved analyzes to have been more than advected. This more at the services and information we proved to mance acute interests on and the related to relate throu

Bhang Your Information We may sense the information we collect through this websile with our employees, agents, contractors or partners in connection with services that these individuals or entities perform for or with us. These agents, contractors or partners are readiced from using these data in any way often than to perform thiss envices. Adapt Pinnam expects our employees and partners to maintin the tush piloted with our boynes with our provide is with information by using reasonable dariinstative, technical and physicial safeguraria. Adapt Pinnam reserves the right to since information to buily adhetical finametion requested is governmential authorities or where required ly line. Insome citorustences, such as where national, safe or company security is all susx. Adapt Pinnam reserves the right to since information to a situ day the context of using a sub-provide is with a proportial governmential authorities. We may also provide information to a titic day it is considered on the sub-provide and uthorities. We may also provide information to a titic day it is considered on the tractical action and advectives. We may also provide information to a titic day it is considered on the association and considers. We may also provide information to a titic day it is considered on the activity and the sub-provide governmental authorities. We may also provide information to a titic day it is considered on the activity and advectives. The sub-table and the provide sub-table to britch the information restense. In which case, we will require any such bayer to agree to test information in accordance with this Privacy Statement. Social Maria Bruines àocial Media Plugins

Social Markin Plugins Our websites may use social media pluginis to enable you to easily share information with others. When you viait our websites, the operator of the social media plugini that is on our website can place a cookie on your computer, enabling that operator to recognize individuals on their website who have previously visited our sites. If you are logged in the social media website white browsing on our website, social media pluginis may allow that social media vebsite to receive directly identifiable information bouty out at shore you have visited our website. Social media vebsite, baget on pluginis site solido the social media vebsite to receive directly identifiable information abouty to that shore you have visited our website. Social media vebsite. Adapt Pharma does not control any of the content from could media pluginis. For more information about social pluginis from social inedia websites, you should refer to hose sites phacy and dats sharing statements.

Do Not Track Some web knowsers may transmit "do-not-track" signals to websites with which the browser communicates. Adapt Pharma webservers do not currently reason to these signals.

outenity requires to trees a grains. Children This sale is not intended for or designed to attract individuals under the age of 13. If you have any useditors ar comments about this Privacy Statement, please contact us by writing to: Adapt Pharma, Inc. 100 Maskonford Read

Building 4, Suite 201 Radnor, PA 19087

Indications and Important Safety Information

NARCAN[®] (naloxone hydrochloride) Nasal Spray is an opiod antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

NARCAN^o Nasal Spray is intended for immediate administration as entergency therapy in settings where optoids 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.

Bate Allumited Efficacy with Partial Aconists or Mated Appriste/Antoportats: Reversal of resolutiony depression caused by partial agonists or mixed agonisticantegoridas, such as bupernorphine and pentazodine, may be incomplete. Larger or repeat does may be required.

Precipitation of Server Opioid Withdrava): Use in patients who are opioid dependent may precipitate opioid withdraval and acute withdrawal syndrome. In nervates, opioid withdraval may be itte-threatening if not recognized and property treated. Monitor for development of opioid withdraval.

usersciences and/or micro and/or micro and/or set and the set of t

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

See Instructions for Use and full prescribing information in the use of this product. See Instructions for Use and full prescribing information in the use of this product. In proof SUBFECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. et I-864-4NARCAN (1-844-482-7228) or FDA at 1-803-FDA-1088 or www.idoa.gov/inedwatch (Z.

Privacy Statement | Terms of Use | Contact Us | Media 🗷 © 2015 ADAPT Pharma, Inc. NARCAN^Ø is a registered trademark licensed to ADAPT Pharma Operations Limited.

ADAPT

NAR4-08-15 ADAPT Pharma, Inc. Radnor, PA

If this is an emergency, call 911. This site is intended for US residents NOW FDA-APPROVED * NARCAN (naloxone HCI) NASAL SPRAY 4mg FOR EMERGENCY TREATMENT OF OPIOID OVERDOSE * NARCAN" NASAL SPRAY Please see Indication and Important Safety Information 4 mg below. 4 mg nasal dose in single spray 🗸 Ready-to-use 🗸 Needle-free Full Prescribing Information Quick Start Guide **Group Purchasers** Press Materials

Terms of Use

By using this site you acknowledge that Adapt Pharma, Inc. is providing the material for informational purposes only and that neither Adapt Pharma nor their agents, affiliates, partners, or licensors are providing the materials to you for the purposes of giving you medical advice. You should not rely on the materials in deciding on a treatment plan, drug usage, or any other medical advice regarding the materials, and Adapt Pharma and their licensors strongly urge that you consult with a physician in connection with any and all treatment options that may be available to you. By using this website, you accept the information, products, and services provided herein "as is." Adapt Pharma makes no express or implied warranty regarding the accuracy, content, completeness, reliability, operability, or legality of information contained within this website, including, without limitation, the warranties of merchantability, fitness for a particular purpose, and non-infringement of proprietary rights. In no event shall Adapt Pharma, or its agents, affiliates, partners, or licensors be liable for any direct, special, indirect, incidental or consequential damages or any damages whatsoever resulting from loss related to the use of our websites, whether in an action of contract, breach of warranty, negligence, or other tortious action arising out of or in connection with the use of the materials contained on this site.

Indications and Important Safety Information

INDICATIONS

DOCKET

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.

<u>Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists</u>: 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.

See Instructions for Use and full prescribing information in the use of this product.

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 🖸 .

Privacy Statement | Terms of Use | Contact Us | Media 🖉

© 2015 ADAPT Pharma, Inc. NARCAN® is a registered trademark licensed to ADAPT Pharma Operations Limited. NAR4-08-15 ADAPT Pharma, Inc. Radnor, PA



LARM Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

If this is an emergency, call 911. This site is intended for US residents. NOW FDA-APPROVED * NARCAN (naloxone HCI) **NASAL SPRAY 4mg** FOR EMERGENCY TREATMENT OF OPIOID OVERDOSE * NARCAN® NASAL SPRAY Please see Indication and Important Safety Information 4 mg below. 4 mg nasal dose in single spray 🗸 Ready-to-use 🗸 Needle-free Full Prescribing Information Quick Start Guide Group Purchasers Press Materials Contact Us If you have a medical emergency, you should immediately call 911 or your local emergency services number. Adapt Pharma, Inc. US Headquarters 100 Matsonford Road Building 4, Suite 201 Radnor, PA 19087 Tel: +1-844-ADAPT-11 (1-844-232-7811)

Indications and Important Safety Information

INDICATIONS

DOCKET

Email: info@adaptpharma.com www.adaptpharma.com

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 and acute withdrawal syndrome. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated. Monitor for development of opioid withdrawal.

<u>Risk of Cardiovascular (CV) Effects</u>: 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.

See Instructions for Use and full prescribing information in the use of this product

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 ⊡*.

Privacy Statement | Terms of Use | Contact Us | Media 🖉

© 2015 ADAPT Pharma, Inc. NARCAN[®] is a registered trademark licensed to ADAPT Pharma Operations Limited. NAR4-08-15 ADAPT Pharma, Inc. Radnor, PA



LARM Find authenticated court documents without watermarks at <u>docketalarm.com</u>.